

## DRUG AND THERAPEUTICS BULLETIN OF NAVARRE, SPAIN

YEAR 2022

VOL 30, Issue 3

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## TOPICAL CORTICOSTEROIDS DURING CHILDHOOD

Topical corticosteroids are a group of medications indicated for the treatment of numerous inflammatory skin processes such as atopic and seborrheic dermatitis and psoriasis. Their molecular structure determines both the potency of their action and the possibility of producing adverse effects. When a powerful action is required, new-generation corticosteroids offer the best safety profile. Children's skin, especially that of infants, allows the absorption of topical medications, thus meaning that it is essential to determine the most appropriate pharmaceutical form in each case and to specify the quantity, mode of application and duration of the treatment. A single daily application is sufficient inmost cases. If applied correctly, the adverse effects are limited, more common locally and mostly reversible after the completion of the treatment. Although these medications are safe, it is common for patients and their families to exhibit worry, reluctance or fear when a topical corticosteroid is prescribed. Therefore it is important to clarify any questions that may arise.

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#### Introduction

Topical corticosteroids are a group of medications indicated for the treatment of numerous inflammatory skin processes.

When selecting the most appropriate, factors depending on the patient, their condition and the characteristics of the drug and its pharmaceutical form must be taken into consideration.

Children, especially those younger than two years, have certain characteristics (greater permeability of the skin, greater body area with respect their body weight) that make them more susceptible to the adverse effects of these medications.

Throughout this document we will review the evidence available regarding the selection and most adequate use of topical corticosteroids in paediatrics.

#### **Objectives and methods**

To review the main characteristics, indications and safety profile for topical corticosteroids to ensure their correct prescription in the paediatric population.

To that end, a search of clinical practice guidelines, systematic reviews, clinical trials and observational studies was performed by consulting PubMed, Cochrane, Up to Date and Epistemonikos.

#### Synthetic topical corticosteroids

Synthetic corticosteroids are obtained by chemical modification of natural corticosteroids. The first synthetic corticosteroid–hydrocortisone–was produced from cortisol. All synthetic topical corticosteroids are derived from it.<sup>1</sup>

These medications possess anti-inflammatory, vaso-constrictor, immunosuppressant and antiproliferative activity.<sup>2,3,4</sup>

#### Classification

Classically, corticosteroids are classified on the basis of their anti-inflammatory potency.





GROUP	POTENCY	ACTIVE SUBSTANCE	
1	Low	Hydrocortisone	
Ш	Intermediate or moderate	Clobetasone butyrate	
"	intermediate of moderate	Hydrocortisone butyrate propionate	
		Betamethasone (dipropionate, valerate)	
		Fluocinolone acetonide	
		Diflucortolone	
		Fluocinonide	
		Diflorasone	
III	High  Mometasone furoate  Methylprednisolone aceponate  Beclomethasone  Hydrocortisone aceponate  Fluticasone propionate  Prednicarbate	Mometasone furoate	
		Methylprednisolone aceponate	
		Beclomethasone	
		Hydrocortisone aceponate	
		Fluticasone propionate	
		Prednicarbate	
IV	Very high	Clobetasol propionate	



The fact that there are different potency tables for different countries, and that different variables are used when establishing the intrinsic potency of a molecule, complicates comparative studies somewhat.<sup>3,7</sup>

#### Risk of adverse effects

The molecular structure of the corticosteroid is related to its activity and the possibility of causing adverse effects.

New generation corticosteroids combine a high local antiinflammatory potency with a good safety profile.<sup>2,3,5,6,8,9</sup>

Table 2 lists those available in Spain.

**Table 2.** New-generation corticosteroids (adapted from reference number 2).

Mometasone furoate					
Fluticasone propionate					
Prednicarbate					
Hydrocortisone aceponate					
Methylprednisolone aceponate					
Hydrocortisone butyrate propionate					

When prescribing a topical corticosteroid, the potency of action and the associated risks must therefore be taken into account (scheme 1).

## Factors determining correct selection of the topical corticosteroid

#### Patient-dependent

#### Age

The skin is an organ that undergoes changes and matures as the child grows.

Children have a much thinner skin than adults and have an up to three times higher surface area/body weight ratio. As such, absorption of the topical corticosteroid is increased, as is the risk of presenting adverse effects. 1,5

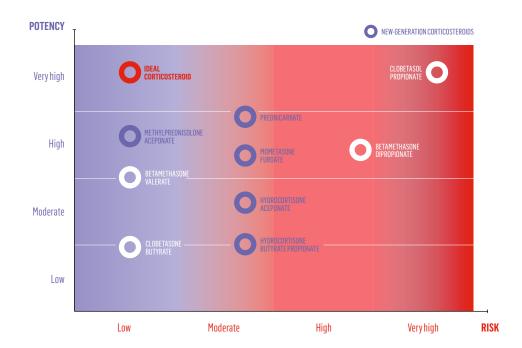
The use of corticosteroids with low and medium potency is therefore most appropriate in children younger than 12 years. Although high potency corticosteroids can be used in paediatric patients, studies of their long-term safety are lacking. 10,11

Infants, whose skin is very different to that of adults (poorly developed stratum corneum, weaker epidermal intercellular junctions, decreased cohesion between the dermis and epidermis and immature collagen), are a particularly sensitive group.<sup>4,5,12</sup>

In children younger than two years, for whom there are insufficient safety studies on the use of topical corticosteroids,  $^{11}$  it is particularly important to consider the age group indications when prescribing (annex 1 and figure 1).



**Scheme 1.** Potency and risks associated with topical corticosteroids (adapted from reference number 5).



IN CHILDREN, ESPECIALLY INFANTS, THE USE OF LOW OR MEDIUM POTENCY CORTICOSTEROIDS IS RECOMMENDED GIVEN THEIR GREATER SUSCEPTIBILITY TO THE ONSET OF ADVERSE EFFECTS.

#### Anatomical region

The topical absorption of drugs varies depending on the thickness of the epidermis and the presence of skin appendages (hair, nails, sweat and sebaceous glands), as can be seen from table 3.

**Table 3.** Anatomical regions ordered from greatest to lowest degree of absorption (adapted from reference number 1).

01	Mucosa
02	Scrotum
03	Eyelids
04	Face
05	Chest and back
06	Arms and thighs
07	Forearms and legs
08	Back of hands and feet
09	Palms and soles
10	Nails

With regard to the region affected, lesions located on the face, folds and genitals are treated with low-potency corticosteroids as these regions have a greater capacity for absorption. Medium potency compounds can be used on the body and limbs, and high potency ones for lesions on the palms and soles of the feet (figure 2).

#### Integrity of the skin

If the integrity of the skin is compromised, absorption of the applied corticosteroid increases. As such, in patients with conditions that cause abnormalities to the stratum corneum (psoriasis, exfoliative dermatitis) or its loss (eczema, erosions and burns), it is preferable to use a low-to-moderate potency corticosteroid as the degree of absorption of the drug may increase by between 10- and 100-fold.<sup>5</sup>

#### Type of disease

Not all inflammatory lesions respond to the use of topical corticosteroids in the same manner. Table 4 lists different conditions based on their sensitivity to these drugs. 3.5.8.14

Figure 1
Prescribing recommendations for topical corticosteroids based on pharmaceutical form and age.

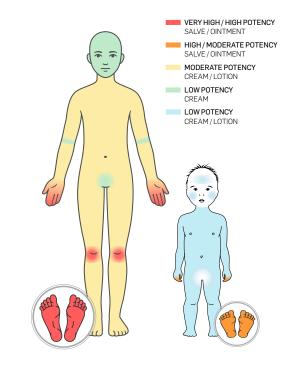
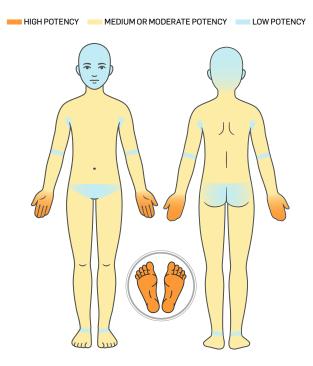


Figure 2
Prescribing recommendations for topical corticosteroids based on the anatomical region affected.



Generally speaking, in sensitive dermatoses it is sufficient to start treatment with a low- or intermediate-potency corticosteroid, whereas in more resistant dermatoses or in the severe forms, it is advisable to start with a high-potency corticosteroid and optimise the treatment based on the clinical response.<sup>12</sup>



SENSITIVE	INTERMEDIATE SENSITIVITY	RELATIVELY RESISTANT	RESISTANT
Seborrheic dermatitis	Mild/moderate psoriasis	Plaque psoriasis	Nail psoriasis
Atopic dermatitis	(affecting <10% body area)	Resistant atopic dermatitis	Acute or chronic urticaria
Nappy rash	Discoid lupus erythematosus	Lichen simplex chronicus	Cutaneous mastocytosis
Sunburn	Discolu tupus er ytriernatosus	Lichen planus	Acne
Contact	dermatitis	Dyshidrotic eczema	Rosacea
Insect	stings	Hyperkeratotic eczema	Perioral dermatitis
Pityriasis rosea (pruritus)	Scabies (post-scabicide)	Alamasia arasta	Keratosis pilaris
Intertrigo	Localised vitiligo	Alopecia areata	lchthyosis
LOW-POTENCY	INTERMEDIATE-POTENCY	HIGH-POTENCY	DO NOT USE

CORTICOSTEROIDS

**Table 4.** Classification of main paediatric dermatoses based on their sensitivity to topical corticosteroids.

#### Dependent on the corticosteroid used

CORTICOSTEROIDS

#### The characteristics of the molecule:

In children under the age of 12 years, the use of low- or medium-potency new-generation corticosteroids is recommended, using those with the lowest effective potency. More potent corticosteroids should be reserved for severe or recurrent dermatoses, and the use of very potent corticosteroids should be avoided given their significantly higher risk of both local and systemic adverse effects. 9

NEW-GENERATION TOPICAL CORTICOSTEROIDS ARE MOST APPROPRIATE IN CHILDREN YOUNGER THAN 12 YEARS OF AGE AS THEY PROVIDE A HIGH POTENCY OF ACTION WITH A LOW PROBABILITY OF ADVERSE EFFECTS.

#### Concentration of the presentation

CORTICOSTEROIDS

A higher drug concentration is not always associated with greater effectiveness as the dose-response curve reaches a plateau for each corticosteroid and, once this is reached, the efficacy does not change, although the risk of adverse effects may increase.<sup>1</sup>

**CORTICOSTEROIDS** 

#### Composition and pharmaceutical form

The duration of action of the corticosteroid and its absorption increase with lipophilicity of the vehicle used<sup>5,6</sup> (table 5).

**Table 5.** Characteristics associated with the different pharmaceutical forms (adapted from references 1 and 17).

ABSORPTION	PRESENTATION	COMPOSITION	ACTION	INDICATIONS	CONTRAINDICATIONS
+ ACTION TIME	Salves	Fatty	Oclusive, hydrating	Dry or squamous lesions. Palms, soles of feet.	Exudative lesions, infection. Hairy regions, folds.
<b>↑</b>	Ointments	Fatty, some water	Lubricant, hydrating	Dry or squamous lesions. Palms, soles of feet.	Acute inflammation, infection. Hairy regions, folds.
<b>↑</b>	Creams	Water, some fat	Refreshing	Inflammatory lesions. Face, folds, limbs.	Exudative, inflammatory lesions. Hairy or large areas.
ACTION TIME	Lotions Emulsions Gels Sprays and foams Shampoos	Water, alcohol, other liquids	Refreshing, tend to dry the skin	Exudative, inflammatory, infected lesions. Hairy regions, large areas.	Wounds, cracked skin.



#### Salves

These are prepared using hydrophobic fatty excipients such as vaseline and paraffin. They form an impermeable layer on the skin that restricts the evaporation of water. As a result, they smooth the skin, hydrate it and exert a barrier action that allows greater absorption of the drug.

They are indicated in very dry dermatoses, lichenified or hyperkeratotic lesions, when there is a need to soften and remove scabs or peeling skin and in regions where the skin is thicker, such as the palms of the hands, soles of the feet, elbows and knees.

Their use in folds or hairy regions is not recommended due to the risk of maceration or folliculitis.

Moreover, they are contraindicated in exudative or infected lesions as their occlusive effect may worsen the infection.  $^{3,15,17}$ 

#### **Ointments**

These use hydrophilic fatty excipients such as polyethylene glycol. As in the case of salves, they exert an emollient action but are not as occlusive. They are useful in the case of squamous lesions or dry skin and are not recommended in infected lesions.<sup>17</sup>

#### Creams

These comprise water and fatty substances. They are indicated for the treatment of dry lesions and dermatosis, although they have a lower occlusive effect than salves and ointments.

Esterified corticosteroids in creams are indicated for non-wet acute and sub-acute childhood dermatoses. This is considered to be the most appropriate presentation for use on the face, skin folds or scrotum.<sup>4,5,17</sup>

### Lotions

These are suspensions or solutions of drugs in water, alcohol or other liquid solvents. These liquids produce a refreshing and drying effect upon evaporation, thus making them useful for the treatment of wet dermatoses and/or pruritus. However, alcohol-containing lotions may cause a burning sensation if the skin is irritated or cracked. In these cases, application of a cream is recommended. They are particularly useful in hairy regions and when large areas of skin need to be treated.

They are available as emulsions, solutions, gel, aerosols, foams and shampoos. Aerosols, foams and shampoos are useful for application to the scalp.  $^{4,14,15,17,18}$ 

The correct choice of vehicle will facilitate a successful treatment. In contrast, an inadequate choice may delay improvement, provoke a worsening of the lesion or the onset of adverse effects. 4.15

Some corticosteroids are presented in combination with moisturising or keratolytic substances that exert an additional beneficial effect.<sup>7,14</sup>

#### Dependent on the mode of application

Whenever a corticosteroid is prescribed it is essential to indicate how it should be applied.

As with any other topical medication, certain hygiene measures, such as washing the hands before and after application and avoiding touching the applicator or not allowing it to touch any surface, including the region of skin to which the product is applied, should be taken into consideration.<sup>17</sup>

The following factors may affect absorption:

#### **Hydration**

Hydration prior to topical application of a corticosteroid increases its penetration up to 10-fold. This is especially important in dermatoses involving cutaneous xerosis, such as atopic dermatitis, where it is recommended to hydrate the skin immediately after a bath or shower and around 15 minutes prior to application of the corticosteroid.

Fatty excipients and urea also promote hydration. 3,14

#### A temperature increase

The heat generated when applying creams, ointments or salves by massaging the skin promotes vasodilation and absorption of the drug.<sup>1,3,14</sup>

#### Occlusion

An increase in the temperature of the occluded region and maintaining its hydration enhance penetration of the corticosteroid and increase its efficacy. Depending on the region, the occlusion time and the corticosteroid used, the potency of action thereof can increase up to 100-fold. Occlusive dressings with topical corticosteroids must not be maintained for more than 12 hours per day. It should also be noted that, whenever systemic absorption is enhanced, the adverse effects also increase.



This technique is applied in localised dermatoses that do not respond well to other regimens and is usually indicated by the dermatologist.

Occlusion is contraindicated in infected regions, intertriginous zones, the face, zones with folliculitis and large areas of skin, It should be avoided when high-potency corticosteroids are applied.<sup>4,15</sup>

#### Quantity of drug

As they have a lower body surface area than adults, children require a significantly lower quantity of topical corticosteroid. It has been calculated that infants require 1/5 of the quantity for an adult, children 2/5 and adolescents 2/3.<sup>14</sup>

Another simple method for estimating the quantity that should be used in each application uses the "fingertip unit" (FTU) (figure 3 and table 6). However, it should be remembered that, in children, the quantity is determined by the size of their own finger.<sup>19</sup>



#### Frequency of application

The stratum corneum of the skin acts as a reservoir, thus allowing gradual penetration of the drug towards deeper layers. Topical corticosteroids are generally once or twice daily. However, it has been reported that reducing

(m)

**Figure 3.** Fingertip measurement units.



the frequency to a single daily application has the same efficacy and also results in fewer adverse effects. 12,15,20,21

It is recommended that the drug be applied in the late evening as the maximum potency is achieved when endogenous steroid levels are lowest (between 8 pm and 4 am).<sup>3.5.6</sup>



Table 6. Dose of topical corticosteroid based on fingertip units [FTUs] (adapted from references 9 and 19).

(my)

FTUs REQUIRED TO COVER IT	FACE AND NECK	ARM AND HAND	LEG AND FOOT	TRUNK ANTERIOR PART	TRUNK POSTERIOR PART (INCLUDES BUTTOCKS)
3-6 months	1	1	1.5	1	1.5
1-2 years	1.5	1.5	2	2	3
3-5 years	1.5	2	3	3	3.5
6-10 years	2	2.5	4.5	3.5	5
Adult	2.5	4	8	7	7



#### **Duration of treatment**

Generally speaking, they should be used for the shortest time possible until the lesion has disappeared. <sup>15</sup>

The recommended duration will depend on:

#### The potency of the corticosteroid (annex 1)

- Low- or medium potency corticosteroids: these are used in regimens of around 10 days, although they can be used for up to six weeks with no significant adverse effects.
  - In children with atopic dermatitis, it has been found that application in a discontinuous regimen for more than 12 weeks is not associated with cutaneous atrophy or cumulative systemic exposure. <sup>11</sup>
- High-potency corticosteroids: should not be used for more than two weeks.<sup>5,22</sup>

#### The region of the body to which they are applied

In the periorbital area, face and folds, treatments longer than two weeks should be avoided given the risk of presenting adverse effects.<sup>14</sup>

#### Evolution of the condition

If a lesion is being treated with a high-potency corticosteroid, it is recommended to change to one with a lower potency if the lesion persists after two weeks<sup>5</sup>.

In cases of recurrent dermatitis with frequent outbreaks in the same region, topical corticosteroids can be used preventively, applying them at weekends to the regions where lesions typically appear. 9,12,15 Studies with this indication prescribe treatment for a maximum of 20 weeks. 23

In long-term treatments, it is recommended to gradually withdraw treatment by reducing the potency of the corticosteroid or the frequency of administration.<sup>4,14</sup>

#### **Adverse effects**

Topical corticosteroids are safer than their systemic counterparts. <sup>15</sup> If used correctly, it is rare for adverse effects to appear, even during long-term treatment. <sup>9</sup> Some factors favour their appearance:

- the use of high-potency corticosteroids
- application to regions with thin skin (eyelids, genitals or skin folds)

- · application to damaged skin
- frequent application
- extent of application
- the use of techniques that increase absorption, such as occlusion (remember that nappies may act as an occlusive dressing).<sup>1,4,15,24</sup>

Local adverse effects are more common than systemic effects. Some, such as genital hypertrichosis or staphylococcus infection, have only been described in the paediatric population.<sup>24</sup>

The majority disappear upon suspension of treatment, except for long-term skin atrophy and stretch marks.<sup>5,24</sup>



The most common adverse effects are shown in table 8.

#### Skin atrophy

This is the most common adverse effect (1/100-1000 patients)<sup>14</sup> and can be caused by any topical corticosteroid. It manifests as loose, transparent, wrinkled and shiny skin due to thinning of the epidermis and changes to the connective tissue in the dermis. In many cases it is reversible upon suspending treatment, although recovery may require several months.<sup>24</sup>

It has been related to continuous application of the corticosteroid, especially if it has a high or very high potency.

In a review involving 22 studies with a total of 2,266 participants with atopic dermatitis, skin atrophy was identified in only 1% of cases. In the majority of such cases it was related to the use of topical corticosteroids with higher potency.<sup>12</sup>

Other studies involving patients with the same condition show, however, that short regimens with high-potency corticosteroids achieve good control of the disease and present a low risk of skin atrophy. 11,25,26

**Table 8.** Adverse effects of topical corticosteroids.

	Atrophy			
	Stretch marks			
	Delayed wound healing			
Cutaneous	Acne-like rash			
	Hyperpigmentation			
	Hypopigmentation			
	Perioral dermatitis			
Vehicle-related	Itching, irritation, contact urticaria, allergic dermatitis			
	Purpura			
	Telangiectasia			
Vascular	Rosacea			
	Facial erythema			
	Hypertrichosis (face and auricle)			
Hair	Alopecia			
	Folliculitis			
	Increased susceptibility to viral and bacterial infections			
Infections	Worsening or masking of infections (tinea incognito)			
	Granuloma gluteale infantum			
Ocular	Glaucoma/cataract/elevated intraocular pressure			
	Suppression of the hypothalamic-pituitary-adrenal axis			
	Cushing syndrome			
Systemia	Hyperglycaemia			
Systemic	Diabetes mellitus			
	High blood pressure			
	Growth alterations			
	Tachyphylaxis			
Others	Rebound effect			
Others	Withdrawal syndrome			
	Contact allergy			



#### Stretch marks

These tend to appear after long-term treatment to the inner thighs, upper arms and breasts, especially in adolescents, <sup>23</sup> and are more common in obese patients. Although they improve upon suspending treatment, they are permanent. <sup>14</sup>

#### Infections

Topical corticosteroid treatment may favour the onset of infections with different microorganisms (bacteria, viruses, fungi) and worsen existing infection, such as

herpes simplex, molluscum contagiosum or infestations such as scabies.

In some infections, such as those caused by dermatophytes, the initial but transient improvement observed may mask the symptoms, thus leading to tinea incognito.<sup>24</sup>

Granuloma gluteale infantum is an entity specific to children. It consists of a persistent purple, granulomatous, papulonodular rash on the buttocks, thighs or fold of the groin in children and can be considered to be a complication of dermatitis in the nappy region. It has been related to the use of high-potency topical corticosteroids,

which appear to reduce the immune response to *Candida spp.* Spontaneous remission within one or two months tends to occur upon suspension of treatment.<sup>24,27</sup>

#### Perioral dermatitis

Perioral dermatitis is a relapsing, papulopustular dermatosis that may be located in the perioral, perinasal, periocular and, more rarely, vulvar, region. Corticosteroids (oral, topical and inhaled) are the most common cause of perioral dermatitis in children and adolescents. It responds to treatment with topical metronidazole and/or erythromycin for 4 to 6 weeks.<sup>28</sup>

#### Vision disorders

Cases of glaucoma, posterior subcapsular cataracts or infections such as herpes simplex have been reported in paediatric patients treated with topical corticosteroids (eye drops or presentations for cutaneous use). <sup>24,29,30,31</sup>

A review of 26 cases (9 cataracts and 21 glaucoma)  $^{29}$  was published in 2015, although only one of these was paediatric. The authors concluded that periorbital application of potent corticosteroids for long periods may cause glaucoma and cataracts, whereas this is not the case for those of lower potency or corticosteroids applied to other parts of the face.

## Suppression of the hypothalamic-pituitary-adrenal axis

Although rare, this is the most commonly reported systemic adverse effect in paediatric patients, especially infants.

It has been particularly associated with the use of high or very high potency corticosteroids for long periods of time or with occlusion, on large areas or with alterations to the skin barrier.

The incidence of adrenal failure secondary to topical corticosteroids is difficult to estimate as subclinical adrenal hypofunction is more common, and this can only be detected by measuring cortisol or ACTH in plasma.

Symptomatic adrenal failure may manifest with non-specific symptoms (tiredness, joint pain and, on occasions, fever or anorexia), Cushing syndrome or, in very rare cases, adrenal crises.<sup>32</sup>

In a meta-analysis from 2018 that analysed a total of 12 trials and 522 children, biochemical suppression of the hypothalamic-pituitary-adrenal axis was reported at 2–4 weeks of topical corticosteroid treatment in 3.8% of cases (2% with low-potency corticosteroids, 3.1% with medium-potency corticosteroids and 6.6% with high

potency). Normal endocrine function was restored at between 1 and 10 weeks from suspension of treatment. The authors concluded that low-potency corticosteroids administered at the recommended dose and for the recommended duration rarely cause a clinically significant suppression of the hypothalamic-pituitary-adrenal axis and complementary tests to evaluate the axis are not recommended in the absence of symptoms indicative of adrenal failure.<sup>33</sup>

#### **Cushing syndrome**

Although the main cause of iatrogenic Cushing syndrome is the administration of oral corticosteroids, it may also present after topical administration.

In this case, patients rarely present all symptoms inherent to this syndrome (purple stretch marks, facial flushing, corticosteroid-related acne, weigh gain, central obesity, rounded face, hypertension, metabolic syndrome, etc.), although they may consult with symptoms such as the appearance of stretch marks or sudden weight gain. The cases published concern infants who received very highly potent corticosteroid (generally clobetasol) to treat nappy rash.<sup>34</sup>

#### Effects on height

An umbrella review compiling safety data regarding the use of topical corticosteroids in atopic eczema from 38 systematic reviews did not find any evidence for growth retardation.<sup>35</sup>

There is also no evidence for a lower bone mineral density in children treated with topical corticosteroids.<sup>36</sup>

#### **Tachyphylaxis**

Tachyphylaxis is a gradual decrease in the effect of a drug when administered continuously or repeatedly. Occasionally, this results in a need to administer more potent corticosteroids to achieve comparable effects, with the concomitant risk of producing more severe adverse effects. However, a lack of efficacy may also be due to problems with patient adherence or changes to the severity of the disease unrelated to treatment.<sup>24</sup>

#### Rebound effect

If a dermatosis has been treated with a high-potency corticosteroid for a long period of time, a relapse may occur when treatment is suspended.

This is more likely when corticosteroids are applied in large quantities or with occlusion.<sup>24</sup>



#### Withdrawal syndrome

Erythema, itchiness, a burning sensation, pain or facial flushing may appear days or weeks after interrupting treatment after use for a long period of time, especially to the face and genitals.<sup>4</sup>

#### Allergic sensitisation

This is generally caused by the components of the pharmaceutical presentation (lanolin, parabens, etc.), although it may also be caused by the corticosteroid itself. It is more common in long-term treatments.<sup>24</sup>

This dermatosis is usually difficult to diagnose as the antiinflammatory effect of the corticosteroid itself masks the symptoms. It is associated with a lack of improvement in in the initial clinical presentation, which often leads to the prescription of new corticosteroids, often of grater potency, thereby chronifying the condition. 15,24

#### **Contraindications**

Before prescribing a corticosteroid, it should be checked that there are no contraindications.<sup>3</sup>

#### Absolute

Known hypersensitivity to the topical corticosteroid or any of the components of the pharmaceutical presentation.

#### Relative

The use of medium- or high-potency corticosteroids should be avoided in children, especially infants, and very high potency corticosteroids are contraindicated.<sup>1</sup>

#### Infections

In general, they should not be used. The exceptions to this are impetiginised eczemas, for which the combination of a corticosteroid with an antibiotic is indicated, and at the onset of treatment of very inflammatory ringworm, where they can be used in combination with an antifungal.  $^{1}$ 

#### Infestation (lice, scabies)

The corticosteroid can be used as symptomatic treatment for the pruritus, although after treatment with the scabicide.

#### **Ulcerated** skin

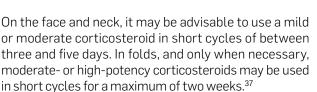
## Use of topical corticosteroids in some paediatric conditions

#### Atopic dermatitis

In this condition it is essential to avoid factors that trigger or worsen outbreaks (exposure to smoke and other pollutants, allergens to which the patient is sensitised, etc.), <sup>10</sup> and to use continuous skin care with emollients. These indications, together with the early use of topical anti-inflammatory drugs, are key to controlling the disease and preventing outbreaks. <sup>23</sup>

Topical corticosteroids are recommended as first-line treatment as they have been shown to be both safe and effective. Of these, those with a better safety profile (new-generation corticosteroids) are recommended. The early use of a corticosteroid with the appropriate potency, in sufficient quantities and at the start of the outbreak, increases the probability of being able to control the inflammation, restore the skin barrier and reduce the subsequent need for new treatment cycles.

The potency of the corticosteroid should be adapted to the severity of the lesions: low for mild eczema, intermediate for moderate atopic eczema and high for severe eczema.<sup>37</sup> On occasions, and for highly exudative lesions, the use of moist dressings with dilute corticosteroids may be an appropriate alternative.<sup>9,23</sup>



Pruritus is the main symptom for evaluating the response to treatment. The administration regimen should not be changed, or treatment suspended, until the pruritus has improved significantly.  $^{23}$ 

The number of daily administrations may vary depending on the severity of the lesions: in mild disease, a corticosteroid can be prescribed once daily or even two or three times per week; and in the severe acute phase twice daily, changing to once daily once the outbreak is in remission.<sup>9</sup>

Once the lesions have disappeared, the corticosteroid should be discontinued gradually. In the case of repeated outbreaks, preventive treatment involving the application of corticosteroids twice a week (for example at weekends) to the affected areas has been shown to be effective. 7.23 This strategy should be reviewed after three or six months to evaluate its effectiveness. 37

Topical calcineurin inhibitor (tacrolimus 0.03% after age 2 years, pimecrolimus 1% after age 3 month) are an alternative to topical corticosteroids for the treatment



of atopic dermatitis. They have an anti-inflammatory activity equivalent to that of medium-potency corticosteroids and an adequate safety profile. Their use is recommended in sensitive areas of the body, such as the face. Moreover, in long-term dermatitis, their use allows corticosteroid use to be reduced.<sup>9</sup>

During acute outbreaks, oral corticosteroids are sometimes used in short regimens of one to two weeks.

In refractive atopic dermatitis, phototherapy or immunosuppressants (ciclosporin A, methotrexate, monoclonal antibodies) are used.<sup>4</sup>

#### Seborrheic dermatitis

The aim of treatment is to control the symptoms (erythema, scaling and pruritus).

Different topical medications, such as antimycotic (ketoconazole, ciclopirox) and keratolytic corticosteroids (salicylic acid) can be used.<sup>38</sup>

In infants with cradle cap, conservative measures, such as frequent washing with a mild shampoo followed by brushing to remove the scales, or application of an emollient (vaseline, oil) to the scalp, followed by brushing, are recommended.

In extensive or persistent cases, a cycle of low-potency topical corticosteroid (one application daily for a week), or the use of cream or shampoo containing 2% ketoconazole (twice a week for two weeks) is recommended.  $^{39,40}$  There is no difference in efficacy between these two treatments in infants and children up to two years of age. The studies published with patients of these ages are limited, and further studies are therefore required to be able to extract recommendations.  $^{41}$ 

In adolescents and adults with seborrhoeic dermatitis of the face or scalp, it has been shown that both topical corticosteroids and topical antifungal agents and calcineurin inhibitors (off-label use) are equally effective for symptom control.<sup>42</sup> In the same group, no difference between treatment with low- or high-potency topical corticosteroids has been observed in the short term, although low potency corticosteroids have been shown to be more effective in the long term.<sup>42</sup>

#### **Psoriasis**

Topical corticosteroids are the first-line treatment for patients with mild psoriasis and can be used in all phases of the disease. <sup>43,44</sup> Their intermediate- and high-potency counterparts can generally be used in children, whereas those of very high potency should be avoided or used for only very brief periods of time.

In general, it is recommended to apply treatment once daily for one or two weeks, subsequently gradually withdrawing treatment in order to reduce the risk of adverse effects.<sup>44</sup>

Other topical treatments that can be used include calcipotriol (vitamin D derivative) or calcineurin inhibitors. Although they are not currently approved as treatments for paediatric psoriasis in Europe, there is some experience with their off-label use.<sup>44</sup>

Vitamin D derivatives have been used with good efficacy and favourable safety and tolerability profiles However, as they have an irritant effect, they are usually used together with emollients or topical corticosteroids. 44,45 In adult patients, the combination of vitamin D analogues with topical corticosteroids has been shown to have a greater anti-inflammatory and lymphoproliferative effect than that observed when used separately, although a similar effect has not been found in children. 43

Calcineurin inhibitors may be useful on the face and folds to avoid the adverse effects associated with long-term corticosteroid use, although their efficacy appears to be lower.<sup>44,45</sup>

The systemic treatment for moderate and severe cases of psoriasis includes phototherapy, retinoids and immunosuppressants. 46,47



#### **Phimosis**

As regards physiological phimosis, there is a very high probability that it resolves spontaneously. It is recommended to perform daily hygiene of the foreskin and apply mild retraction exercises. Topical corticosteroids can be used to achieve adequate retraction in some cases. 46

Circumcision is the traditional treatment for pathological phimosis.<sup>47</sup> However, topical corticosteroids are currently considered to be an effective, safe and less invasive option than surgery.<sup>48,49</sup>

The most commonly used corticosteroid is betamethasone. Clobetasol, triamcinolone, fluticasone propionate and hydrocortisone are also used. 46.47

The success rate for corticosteroids in the different trials carried out exceeds 80%. <sup>48</sup> The best result appears to be achieved with betamethasone cream 0.05% (success rate of 95%). The frequency of application varies between once and twice daily, and the duration of treatment between 4 and 6 weeks. No local or systemic adverse effects have been observed. <sup>46</sup>

A phimosis recurrence rate of 17% has been estimated. To reduce this, it is recommended to continue with retraction of the foreskin and daily hygiene.  $^{48,50}$ 

#### Cortico-phobia

Cortico-phobia is the worry, reluctance or fear of using corticosteroids even though they are safe and effective when administered appropriately.<sup>9</sup>

The frequency of this phenomenon varies between 21% and 80%, depending on the source consulted,  $^{51}$  and it has been estimated that approximately one third of parents are reluctant to administer topical corticosteroids to their children,  $^{52}$ 

It is important that healthcare professional discuss the worries of the patient or their family regarding the risk of corticosteroids.

Various proposals for detecting cortico-phobia have been validated, ranging from simply asking parents "would you agree to use corticosteroids on your child's skin?" to other, more complex alternatives, such as the TOPICOP questionnaire.  $^{54}$ 

The most common worries are the possibility that topical corticosteroids "pass into the blood", the presentation of adverse skin effects, such as thinning of the skin, developmental and growth abnormalities, and the "possibility of applying too much cream". <sup>53,55,56</sup> The belief that topical corticosteroids are dangerous and that treatment has more disadvantages than advantages has also been detected. <sup>56</sup>

A fear of using topical corticosteroids may trigger a vicious circle that leads to treatment failure: the lack of adherence may result in relapse, thereby reducing confidence and, therefore, decreasing adherence still further. The has been estimated that, as a result of the fear of applying topical corticosteroids, only 33% of atopic dermatitis patients comply with the regimen prescribed. 53,57,58

Expert recommendation highlight the importance of healthcare professionals discussing the worries of the patient or their family, answer questions that may arise

and explain the benefits and risks of topical corticosteroid treatment, emphasising that the benefits outweigh the possible harm when applied correctly.<sup>23,37,53,55</sup>



IT IS IMPORTANT TO ASK ABOUT THE POSSIBLE DOUBTS OR RELUCTANCE OF THE PATIENT OR THEIR FAMILY WHEN PRESCRIBING A TOPICAL CORTICOSTEROID AND TO PROVIDE THE INFORMATION REQUESTED.

#### **Conclusions**

It is important to bear in mind the characteristics of each corticosteroid (potency and pharmaceutical form) and each patient (age, type and location of the lesion) to make an adequate prescription.

New-generation topical corticosteroids are most appropriate in children aged less than 12 years as they combine a high potency of action with a low probability of adverse effects.

It is important to specify the mode of application: the quantity (how much), when to apply it (once daily will generally be sufficient), how to apply it and the duration of treatment (until when).

The adverse effects are rare and mostly reversible upon suspending treatment.

It is important to ask about the possible doubts or reluctance of the patient or their family when prescribing a topical corticosteroid and to provide the information requested.



### Annex 1

## Topical corticosteroids available in Spain

 $[New-generation\,corticos teroids\,are\,highlighted\,in\,red]$ 

	FORMULATION/VEHICLE	BRAND NAMES	OTHER CONSIDERATIONS	
GROUP 1 LOW POTENCY				
	Cream	Calmiox® 5 mg/g crema		
		Hidrocisdin® 5 mg/g crema	Indication to consult the physician in <12 years	
Hidrocortisone	Foam	Calmiox® 5 mg/g		
	Ointment	Dermosa Hidrocortisona® 10 mg/g	Indicated in >12 years, care in children	
	Emulsion	Lactisona® 10 mg/mL emulsión cutánea	No age limit indicated	
GROUP 2 INTERMEDIATE OR MODERA	TE DOTENCY			
Clobetasone butyrate	Cream	Emovate® 0,5 mg/g	No age limit indicated	
Hidrocortisone butyrate propionate	Cream	Nutrasona®1mg/g	Do not use in < 2 years	
	Oreani	Nadasona 1mg/g	Do not use in < 2 years	
GROUP 3 HIGH POTENCY				
Betamethasone	Cream	Celecrem® 0,5 mg/g		
		Celecrem®1mg/g		
	Emulsion	Betametasona dipropionato 1 mg/g		
	Linutaion	Betametasona dipropionato 2 mg/g		
		Betametasona dipropionato 5 mg/g		
Betamethasone dipropionate	Cream	Diproderm® 05 mg/g		
		Betametasona dipropionato 5 mg/g		
	Ointment	Diproderm® 05 mg/g		
	Solution	Diproderm® 05 mg/g	Contraindicated in younger than 1 year	
	Cream	Betnovate®1mg/g		
Betamethasone valerate	Solution	Betnovate®1mg/g		
	Column	Fluocid forte® 2 mg/g		
	Cream	Synalar® 0,25 mg/g		
Fluocinolona acetonide		Synalar forte® 2 mg/g		
		Synalar Gamma 0,1 mg/g		
	Gel	Gelidina® 0,25 mg/g		
	Foam	Synalar® 0,25 mg/g		
Diflucortolone	Cream	Claral®1mg/g	Contraindicated in < 4 months	
			Not recommended in < 2 years	
Fluocinonide	Cream	Novoter® 0,5 mg/g	Contraindicated in < 1 year	
Diflorasone	Gel	Murode® 0,5 mg/g	Indicated in > 1 year	
		Elocom®1mg/g		
	Cream	Mometasona® EFG 1 mg/g		
	Ointment	Elocom®1mg/g		
Mometasone furgate		Mometasona® EFG1 mg/g	Contraindicated in < 2 years	
Hometasone iui oate		Elocom®1mg/g	Contraindicated in < 2 years	
	Solution	Mometasona® EFG1 mg/g		
	Foundation			
	Emulsion	Monovo®1 mg/g		
	Cream	Adventan® 1 mg/g		
		Lexxema®1 mg/g		
	Emulsion	Adventan® 1 mg/g		
	Emutsion	Lexxema®1 mg/g		
		Adventan® 1 mg/g		
Methylprednisolone aceponate	Ointment	Lexxema®1 mg/g	Do not use in < 4 months	
		Adventan® 1 mg/g		
	Salve	Lexxema®1 mg/g		
		Adventan® 1 mg/g		
	Solution	Lexxema®1 mg/g		
	Cream			
	Salve	Menaderm simple® 0,25 mg/g	Contraindicated in < 1 year	
Beclomethasone		Menaderm simple® 0,25 mg/g	Not indicated in < 5 years	
	Emulsion	Menaderm simple® 0,25 mg/mL		
Hydrocortisone aceponate	Cream	Suniderma® 1,27 mg/g	No age limit indicated	
, sor asone assponate	Ointment	Suniderma® 1,27 mg/g		
Flutionene ny!t-	Croom	Flunutrac® 0,5 mg/g	Use not indicated 's advers	
Fluticasone propionate	Cream	Fluticrem® 0,5 mg/g	Use not indicated in < 1 year	
		Batmen® 2,5 mg/g		
	Cream	Peitel® 2,5 mg/g		
		Batmen® 2,5 mg/g		
	Ointment	Peitel® 2,5 mg/g		
Prednicarbate		Batmen® 2,5 mg/g	Not recommended in < 6 years	
	Solution			
		Peitel® 2,5 mg/g		
	Salve	Batmen® 2,5 mg/g		
		Peitel® 2,5 mg/g		
GROUP 4 VERY HIGH POTENCY	Shampoo	Clobex® 500 μg/g	Contraindicated in < 2 years	
GROUP 4 VERY HIGH POTENCY				
	Solution	Clobisdin® 500 μg/g	Weekly check-up in ages 2 to 18 years	
GROUP 4 VERY HIGH POTENCY	Solution Cream	Clobisdin® 500 μg/g Clovate® 0,5 mg/g	Weekly check-up in ages 2 to 18 years  Contraindicated in < 1 year	



# Annex 2 **Topical corticosteroids available in Spain**INFORMATION SHEET



#### -What are corticosteroids?

They are a class of hormones that we all produce in glands located just above the kidneys. The most important is cortisol. Corticosteroids are essential for life and regulate numerous bodily functions.

#### -What are they used for?

Drugs used to treat various inflammatory diseases, such as asthma or dermatitis, have been developed from natural corticosteroids. Topical corticosteroids are those administered to the skin or mucosa.

#### —When are they used?

Corticosteroids can only be used when indicated by a doctor and always in accordance with the instructions regarding the frequency, form of application and duration of treatment.

Not all corticosteroids are the same. They are available in different potencies and different presentations. To choose the most appropriate, the type of lesion, region affected or age of the patient, amongst other aspects, are taken into account.

#### - Are they safe and effective?

When applied correctly, they are very safe and effective drugs, even for children. The amount of drug that may pass into the blood is minimal and adverse effects are rare if applied correctly.

When applied correctly, they are very safe and effective drugs, even for children.

## —What are the risks when they are applied incorrectly?

When used incorrectly (in a greater quantity than indicated, or with a greater potency than required, or for a longer period than needed), they may cause adverse and harmful health effects. They may cause skin abnormalities such as atrophy, stretch marks or rash, eye abnormalities such as cataracts and, very rarely, they may cause more important health problems, such as the body stopping producing cortisol.

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#### ISSN

1138-1043

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