

PATIENT INFORMATION LEAFLET

Timodine[®] Cream

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Timodine Cream is and what it is used for
2. What you need to know before you use Timodine Cream
3. How to use Timodine Cream
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1. What Timodine Cream is and what it is used for

Timodine Cream is used to treat inflamed skin conditions, particularly where the fungal infection *Candida albicans* can occur.

Timodine Cream contains four different medicines called nystatin, hydrocortisone, dimeticone and benzalkonium chloride.

- Nystatin is an antifungal agent which kills *Candida albicans*
- Hydrocortisone is a mild corticosteroid (or steroid) which fights the inflammation that causes redness, swelling and itchiness
- Dimeticone is a water-repellent which stops wetting and chafing
- Benzalkonium chloride is an antiseptic which kills bacteria.

Where two folds of skin rub together, chafing can occur, leading to a sore inflamed area of skin. This particularly happens in places such as the groin or under the breasts where frequent sweating occurs. This combination of irritated skin and wetness is called intertrigo. The same condition happens under babies' nappies and is known as nappy rash. In both intertrigo and nappy rash the inflamed skin is easily infected by germs, in particular a fungus called *Candida albicans*. Timodine Cream is specially formulated to ease the soreness and treat the infections in **intertrigo and inflamed nappy rash**.

Timodine Cream can also be used to treat the following skin conditions when there is infection with *Candida albicans*:

- **Eczema**
- **Hand dermatitis** (skin irritation caused by chemicals such as washing powders)
- **Seborrhoeic dermatitis** (inflammation of the scalp with excessive dandruff scales and oily secretions)
- **Pruritis ani and vulvae** (irritation of the external area around the anus and vagina).

2. What you need to know before you use Timodine Cream

Do not use Timodine Cream on you or your child:

- if you or your child are allergic (hypersensitive) to nystatin, hydrocortisone, dimeticone 350, benzalkonium chloride solution or any of the ingredients in Timodine Cream (see Section 6 Contents of the pack and other information)
- on any untreated bacterial, fungal or viral skin infections
- on ulcerated skin
- to treat a skin condition called perioral dermatitis. This is a red spotty rash around your mouth or chin
- to treat a skin condition called rosacea. This is redness and inflammation over your nose, cheeks, chin or forehead
- near the eyes
- under dressings on large areas of the body.

Do not use Timodine Cream for longer than 7 days on infants unless your doctor tells you to

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you use Timodine Cream.

Warnings and precautions

- Talk to your doctor before using Timodine Cream:
 - if you are pregnant or breast feeding
 - if you are elderly
 - if using on a newborn baby
 - if you or your child have pruritis (an itchy skin condition)
 - if you or your child have liver disease
 - on infected wounds, broken skin, thin/ raw skin or acne
- Avoid prolonged use of Timodine Cream on the face
- Prolonged use of Timodine Cream could increase the likelihood of the cream stopping being effective for you, and of you developing an allergic reaction to the cream
- If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. If you experience a recurrence of your condition shortly after stopping

treatment, within 2 weeks, do not restart using the cream without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

- Increased absorption of the cream may occur if the cream is used on thin/ raw skin, on areas where two skin areas touch or rub together, or under dressings. Thinning of the skin is more likely to occur if the cream is used under dressings
- If you are using Timodine Cream for nappy rash make sure you speak to your doctor about how you should use the cream. Nappies can make it easier for the ingredients of the cream to pass through the skin and it is possible to accidentally end up using too much cream.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you use Timodine Cream.

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Hydrocortisone is classed as a mild corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

Do not smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce build-up but not totally remove it.

Other medicines and Timodine Cream

Please tell your doctor or pharmacist if you are taking or have recently taken/used any other medicines, including medicines obtained without a prescription.

If you are using other skin creams at the same time as Timodine Cream, make sure you leave several minutes between applying the different creams.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

There is not enough information to show that Timodine Cream can be used safely during pregnancy and breast-feeding. If you are pregnant or breast-feeding, only use Timodine Cream if advised by your doctor.

Important information about some of the ingredients of Timodine Cream

Timodine Cream contains:

- Butylated hydroxyanisole (E320) – which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes
- Cetostearyl alcohol and sorbic acid – both of these ingredients may cause local skin reactions (e.g. contact dermatitis)
- Propyl hydroxybenzoate (E216) and methyl hydroxybenzoate (E218) – both of these ingredients may cause allergic reactions (possibly delayed)
- Propylene glycol (E1520) which may cause skin irritation.

3. How to use Timodine Cream

Always use Timodine Cream exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure. A finger-tip length of cream should be enough for each inflamed area. It is important to apply the cream thinly, to the affected area only.

For intertrigo, eczema, hand dermatitis, seborrhoeic dermatitis, pruritis ani and vulvae:

Apply a thin layer of Timodine Cream to the sore area and rub into the skin gently until the cream disappears. Repeat the treatment three times a day until the skin is healed.

For severe nappy rash: Remove the soiled nappy, then clean and dry your baby's skin. Rub a thin layer of Timodine Cream into the sore areas until the cream disappears. Repeat the treatment after every nappy change.

- **Do not use Timodine Cream for more than 7 days, unless your doctor tells you to.**

You may find a yellow stain on terry cotton nappies after using Timodine Cream. This will disappear after soaking in bleach or nappy solution followed by rinsing and normal washing.

If you use more Timodine Cream than you should

Over-use of any corticosteroid cream can result in:

- irreversible skin thinning, stretch marks, and dilated blood vessels near the surface of the skin
- the body absorbing too much steroid and the adrenal glands may stop working properly. Symptoms of this may include tiredness, depression and anxiety
- a condition where levels of steroid hormone become too high in the body, known as Cushing's syndrome. Symptoms include a puffy and rounded face that is also red, stretch marks and acne.

Timodine Cream is for external use only and should only be applied to the skin. If you accidentally swallow the cream this may cause nausea and vomiting or diarrhoea. If the cream is swallowed, drinking a glass of water or

milk may be helpful. You should tell your doctor at once or contact your nearest accident and emergency department. Show any left-over medicines or the empty container to your doctor.

If you forget to use Timodine Cream

In the case of a missed application, simply apply when the next dose is due.

If you stop using Timodine Cream

A worsening of symptoms can sometimes occur. If this happens to you, tell your doctor or pharmacist.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some people may be allergic to Timodine Cream. If you or your child experience an allergic reaction you should stop using Timodine Cream and tell your doctor straight away or contact the accident and emergency department of your nearest hospital. Signs of an allergic reaction may include:

- severe rash
- swallowing or breathing problems
- swelling of your lips, face, throat or tongue
- weakness, feeling dizzy or faint
- nausea.

Other possible side effects:

- thinning of the skin
- stretch marks
- dilated blood vessels near the surface of the skin
- red spotty rash around your mouth or chin
- acne, or your acne may become worse
- allergic or irritant skin reactions
- loss of colour in the skin where the cream is used
- excessive hair growth
- the appearance of red or purple discolorations on the skin that do not blanch on applying pressure
- spread and worsening of untreated infection
- redness and inflammation over the nose, cheeks, chin or forehead
- adrenal glands may stop working properly. Symptoms of this may include tiredness, depression and anxiety
- Cushing's syndrome (a condition where levels of steroid hormone become too high in the body). Symptoms include a puffy and rounded face that is also red, stretch marks and acne.

- steroid withdrawal reaction: if used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after stopping treatment, with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Timodine Cream

Keep out of the sight and reach of children.

Do not use Timodine Cream after the expiry date which is stated on the carton and on the tube (EXP). The expiry date refers to the last day of that month.

Store Timodine Cream below 15°C.

Do not use Timodine Cream if you notice a change in the colour or feel of the cream.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Timodine Cream contains

The active ingredients in this medicine are nystatin 100,000 IU/g, hydrocortisone 0.5% w/w, dimeticone 350 10% w/w and benzalkonium chloride solution 0.2% w/w.

The other ingredients are dibutyl phthalate, glycerol stearate, PEG 100 stearate, purified water, stearic acid, sodium metabisulphite, cellulose nitrate, cetostearyl alcohol, butylated hydroxyanisole compound (containing butylated hydroxyanisole (E320), propyl gallate, citric acid and propylene glycol (E1520)), methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), and sorbic acid.

What Timodine Cream looks like and contents of the pack

Timodine Cream is a pale yellow cream.

Timodine Cream comes in aluminium tubes of 5.5g, 7.5g and 30g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is: Alliance Pharmaceuticals Limited
Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB, UK.

Timodine Cream is manufactured by: Conforma N.V., Zenderstraat 10, B-9070
Destelbergen, Belgium.

The information in this leaflet applies only to Timodine Cream. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

This leaflet was last revised in February 2024

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