



Patient Information Leaflet

Salibet™ 0.05% w/w / 3% w/w Ointment

Betamethasone dipropionate / Salicylic acid

Read all of this leaflet carefully before you start using this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Salibet™ Ointment is and what it is used for
2. Before you use Salibet™ Ointment
3. How to use Salibet™ Ointment
4. Possible side effects
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6. Further information

1. What Salibet™ Ointment is and what it is used for

Salibet™ Ointment contains two active ingredients, betamethasone dipropionate and salicylic acid.

Betamethasone dipropionate is one of a group of medicines called topical corticosteroids. It is classified as a "potent corticosteroid". These medicines are put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems. Salicylic acid softens the top layer of scales on the surface of the skin, which are caused by your skin problem. This allows the betamethasone dipropionate to reach the diseased skin underneath to help heal it.

In adults and children, Salibet™ Ointment is used to treat skin conditions where the outer surface of the skin is covered by a layer of scales. Your ointment will remove the layer of scales and reduce the redness and itchiness caused by your skin problem.

2. Before you use Salibet™ Ointment

Do not use Salibet™ ointment

- if you are allergic to betamethasone dipropionate, salicylic acid or any of the other ingredients in this medicine (listed in section 6).
- on any other skin problem as it could make it worse especially rosacea (a skin condition affecting the face), acne, dermatitis (skin inflammation) around the mouth, genital itching, nappy rash, cold sores, chickenpox or other skin conditions.

Warnings and precautions

Talk to your doctor or pharmacist before using Salibet™ ointment.

This medicine should not be used under bandages or plasters.

Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids used on the skin, especially in infants and children.

Children

If the ointment is used more often than it should, or more than prescribed, it can affect some of your child's hormones. This may affect their growth and development.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

3. How to use Salibet™ Ointment

Always use Salibet™ Ointment exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Recommended dose

Usually for adults and children, a thin layer of Salibet™ Ointment should be gently rubbed on the affected area of skin twice a day.

You should always follow these instructions when using Salibet™ Ointment:

- Do not use the ointment on your face for more than 5 days.
- Do not use a large amount of ointment on large areas of the body for a long time (for example every day for many weeks or months).
- Avoid getting the ointment in your eyes.

Use in children

Use as stated above. Do not use this ointment on any part of your child's body for more than 5 days. Do not put the ointment under your child's nappy, as this makes it easier for the active ingredients of the medicine to pass through the skin and possibly cause some unwanted effects.

If you use more Salibet™ Ointment than you should

If you use the ointment more often than you should, or on large areas of your body, it can affect some of your hormones. In children this may affect their growth and development. It also may cause you to feel and/or be sick and to hear ringing in your ears. If you have not used the ointment as you were told to do and have used it too often and/or for a long time, you should tell your doctor.

If you swallow Salibet™

If you (or somebody else) accidentally swallow the ointment, it should not cause any problems. However, if you are worried, you should see your doctor.

If you forget to use Salibet™ Ointment

If you forget to use your ointment at the right time, use it as soon as you remember, then carry on as before.

If you stop using Salibet™ ointment

If you have been using the ointment for a long time and your skin problem seems to have got better, you should not suddenly stop using the ointment. If you do, you may find that your skin becomes red and you may notice stinging or burning. To avoid this, you should speak to your doctor who will gradually reduce how often you need to use the ointment until you stop treatment altogether.

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.

Most people find that when the ointment is used correctly, it does not cause any problems. However, if you use the ointment more often than you should, it can cause the following:

- Thinning of the skin, stinging, blistering, peeling, swelling, itching, burning, skin rash, dryness of the skin and you may notice red marks. This can happen more easily in infants and children.
- Inflammation of the hair follicles, excessive hair growth, reduced skin pigmentation and allergic skin reactions.
- Dermatitis (skin inflammation), a condition brought on by the skin reacting to outside agent e.g. detergents, causing the skin to become red and itchy.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Salibet™ Ointment

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use Salibet™ after the expiry date which is stamped on the pack and tube.

Advice to be used within 3 months of tube opening.

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

6. Further information

What Salibet™ Ointment contains

- The active substances are betamethasone dipropionate equivalent to betamethasone 0.05% w/w and salicylic acid 3.0% w/w.
- The other ingredients are liquid paraffin & white soft paraffin (white petroleum jelly).

What Salibet™ Ointment looks like and contents of the pack

- Salibet™ Ointment is a white to off white homogenous ointment
- Salibet™ Ointment comes in aluminium collapsible tube of 30g.

Marketing Authorisation Holder and Manufacturer

Jamjoom Pharmaceuticals Co.,
Jeddah, Saudi Arabia.
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Website: www.jamjoompharma.com

To report any side effect(s):

• Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
 - o Fax: +966-11-205-7662
 - o Call NPC at +966-11-2038222.
 - o Exts: 2317-2356-2353-2354-2334-2340.
 - o Toll free phone: 8002490000
 - o E-mail: npc.drug@sfd.gov.sa
 - o Website: www.sfd.gov.sa/npc

• Other GCC States:

- Please contact the relevant competent authority.

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THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists



Salibet™ is a quality product manufactured by:



P.O.Box 6267 Jeddah - 21442- Saudi Arabia

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190 x 280 mm