

PACKAGE LEAFLET: INFORMATION FOR THE USER

NPA001076



Duofilm

Cutaneous Solution
salicylic acid 16.7% w/w
lactic acid 15.0% w/w



Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Duofilm carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or doctor if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Duofilm is and what it is used for
2. Before you use Duofilm
3. How to use Duofilm
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1. What Duofilm is and what it is used for

The name of your medicine is Duofilm. It contains two medicines called salicylic acid and lactic acid. It works by softening the skin of a wart, causing it to peel off.

Duofilm is used to treat warts.

- A wart is an infection in the top layers of the skin. It is caused by a virus.
- Warts can be spread when the virus touches damaged skin.
- It is more likely to spread in places which are warm and moist. This is why one of the most common places to catch warts is swimming pools.
- It can take from a few weeks to several months for the wart to appear.

2. Before you use Duofilm

Do not use Duofilm:

- if you are allergic to the salicylic acid, lactic acid or any of the other ingredients of Duofilm (listed in Section 6).
- on open skin wounds, moles, birthmarks, warts on your face, genital warts, warts with hair growing from them, warts with red edges or with an unusual colour.

Do not use Duofilm if the above applies to you. If you are not sure, talk to your doctor or pharmacist before you start using Duofilm.

Take special care with Duofilm:

- Duofilm is for external use only.
- Don't get Duofilm in your eyes, nose, or mouth, or on the genital and anal areas. If you do get Duofilm in your eyes, flush with water for 15 minutes.
- Do not inhale the vapour.
- Ensure you keep Duofilm out of the reach of children, to avoid accidental ingestion.
- Only apply Duofilm to the wart and not to the normal skin surrounding the wart. Do not apply to reddened, inflamed or damaged skin.

Speak to your doctor before using Duofilm if:

- you are diabetic or suffering from poor circulation in your hands or feet.
- the warts cover a large area of your body (more than 5cm²).
- you are using another medicine on the area.
- the patient is a child or teenager who has or has just had chickenpox, flu, or another viral infection.

Pregnancy and breast-feeding

Talk to your doctor before using any medicine if you are pregnant, trying to become pregnant or breast-feeding. Do not use Duofilm on your chest if you are breast-feeding.

3. How to use Duofilm

If this medicine is from your doctor or pharmacist, do exactly as they have told you. Otherwise, follow the instructions below. If you do not understand the instructions, or you are not sure, ask your doctor or pharmacist.

Using Duofilm

- Use Duofilm once a day, preferably at bedtime, using the brush in the pack.
 - Keep using Duofilm until the wart has completely gone. When it has gone you will be able to see the lines of your skin again (called 'ridge lines').
 - It may take 4 to 8 weeks to completely remove your wart. Speak to your doctor if the wart has not cleared after 12 weeks.

How to use Duofilm

1. Remove any plasters.
2. Soak the warts in hot water for five minutes.
3. Dry the area with your own towel.
4. Rub the top of the warts carefully with a nail file, pumice stone, emery board or coarse washcloth, with care taken not to cause bleeding.
5. Then put on enough Duofilm to cover the warts. Try not to get it on the normal skin around the warts.
6. Let the Duofilm dry thoroughly.
7. Cover the wart with a plaster if it is large or on your foot.

To stop warts spreading to others

Remember that warts can spread to others.

- Only use your own towel.
- If your warts are on the bottom of your feet, do not walk around bare foot.

Children

Duofilm is not recommended for use in children under 2 years of age. Children under 12 years should only use the medicine with help from an adult.

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

If you use more Duofilm than you should

Excessive use could cause irritation of the skin. If this occurs, use more sparingly or apply less frequently. If you swallow Duofilm accidentally, seek immediate medical advice.

4. Possible side effects

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

Stop use and speak to your doctor or pharmacist if skin irritation develops.

Duofilm may cause allergic skin reactions (allergic dermatitis), rash, dryness, scaling, irritation, itching, swelling, burning sensation, redness, excessive skin growth, discolouration of the skin, pain and hypersensitivity at the site of application.

If you accidentally apply Duofilm to healthy skin you may experience blistering and skin exfoliation.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAPharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Duofilm

- Keep out of the sight and reach of children.
- Do not use Duofilm after the expiry date stated on the bottle and carton (after "Exp:"). The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Duofilm is highly flammable, keep it away from naked flames.
- 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 Duofilm contains

- The active substances are lactic acid 15.0% w/w and salicylic acid 16.7% w/w.
- The other ingredient is flexible collodion (contains pyroxylin, colophony, virgin castor oil, ethanol and ether).

What Duofilm looks like and the contents of the pack

Duofilm is a clear yellow to amber coloured cutaneous solution (for use on the skin). Duofilm is supplied in bottles of 15ml.

Product Authorisation Holder and Manufacturer

Product Authorisation Holder:
GlaxoSmithKline Consumer Healthcare (Ireland) Limited,
12 Riverwalk, CityWest Business Campus, Dublin 24,
Ireland.

Manufacturer(s):

Delpharm Bladel B.V.
Industrieweg 1, 5531 AD BLADEL, The Netherlands
or Stiefel Laboratories (Ireland) Ltd.
Finisklin Business Park, Sligo, Ireland

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