PACKAGE LEAFLET: INFORMATION FOR THE USER





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 get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1. What Warticon Cream is and what it is used for
- 2. Before you use Warticon Cream
- 3. How to use Warticon Cream
- 4. Possible side effects
- 5. How to store Warticon Cream
- 6. Further information

1. What Warticon Cream is and what it is used for

Warticon Cream contains a medicine called podophyllotoxin. This is a plant extract which belongs to a group of medicines called 'antivirals'.

Warticon Cream is used to treat genital warts. It is used for warts on the penis in men and external warts on the vagina in women.

2. Before you use Warticon Cream

Do not use Warticon Cream if:

- you are allergic to podophyllotoxin or any of the other ingredients of Warticon Cream (listed in Section 6).
- you are pregnant or breast-feeding a baby
- your warts surround an open wound (such as after surgery).
- · the patient is a child
- you are already using another medicine containing podophyllotoxin.

Do not use Warticon Cream if any of the above apply to you. If you are not sure, ask your doctor or pharmacist before using this medicine.

Take special care

Talk to your doctor before using this medicine if:

- any of your warts are bigger than a 4 centimetre area (approximately the size of a postage stamp). You may need to have this medicine applied by a trained health professional.
- If you are not sure, talk to your doctor or pharmacist.

Important information about some of the ingredients in Warticon Cream:

Warticon Cream contains butylated hydroxyanisole (E320), sorbic acid, stearyl and cetyl alcohols which may cause local skin reactions (e.g.contact dermatitis). Butylated hydroxyanisole may also cause irritation to the eyes and mucous membranes.

Warticon Cream also contains methyl and propyl parahydroxybenzoates, E218 and E216, which may cause allergic reactions (possibly delayed).

3. How to use Warticon Cream

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

Using Warticon Cream

- Apply Warticon Cream twice a day, in the morning and evening for 3 days.
- Do not apply any cream for the next 4 days. This completes one treatment course.
- If you still have any warts remaining 7 days after you started using the cream, repeat the treatment course (twice a day for 3 days followed by 4 days where you do not use the cream).
- A maximum of 4 treatment courses may be applied.
- If any warts remain after 4 treatment courses consult your doctor.

How to apply Warticon Cream

- 1. Wash the affected areas with soap and water. Dry the area well with a clean towel.
- It may help you to view the area to be treated, if you sit down and place the mirror as shown in the diagram below.
- Using a fingertip, apply Warticon Cream to cover each wart. Use only enough cream to cover each wart.
- 4. Rub the cream into the wart. Be careful not to get the cream onto healthy skin. If this happens, wash the cream off with soap and water.
- 5. Wash your hands thoroughly.
- 6. Make sure you have screwed the lid back on tightly.



If you get Warticon Cream in your eyes or if you swallow it

- If you get Warticon Cream in your eye, rinse the eye thoroughly with water and talk to your doctor.
- If you accidentally swallow some of the cream see your doctor or go to hospital straight away. Take the tube of cream with you so that the doctor knows what you have swallowed.

Having sex when using Warticon Cream

You should not have sex when you are still treating your warts. You should wait until your warts have gone and your skin has healed. If you do have sex, you must use a condom.

4. Possible side effects

Like all medicines, Warticon Cream can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

 irritation, burning and tenderness. If these happen, they are likely to occur on the second or third day of treatment as the warts begin to disappear. In most cases these effects are mild and will pass.

If these effects do not go away and cause severe

discomfort, stop using the medicine and see your doctor.

If you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Warticon Cream

- Keep out of the reach and sight of children
- Do not use Warticon Cream after the expiry date which is stated on the tube and carton (after "Exp:"). The expiry date refers to the last day of that month.
- Warticon cream does not require any special storage conditions.
- 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 Warticon Cream contains

- The active substance is podophyllotoxin 0.15% w/w (1.5 miligram per gram of Warticon Cream).
- The other ingredients are: purified water, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sorbic acid, phosphoric acid, stearyl alcohol, cetyl alcohol, isopropyl myristate, liquid paraffin, fractionated coconut oil, butylhydroxyanisole (E320), macrogol – 7 stearyl ether, macrogol – 10 stearyl ether.

What Warticon Cream looks like and contents of the pack

Warticon Cream comes in tubes containing 5 grams of a white cream.

A small mirror is provided in each pack.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

GlaxoSmithKline UK Limited, Trading as Stiefel, Stockley Park West, Uxbridge, Middlesex UB11 1BT, UK GlaxoSmithKline (Ireland) Limited Stonemasons Way, Rathfarnham Dublin 16, Ireland. Trading as Stiefel

Manufacturer:

Stiefel Laboratories (Ireland) Ltd. Finisklin Business Park, Sligo, Ireland

Date of preparation: June 2011

PL 19494/0073 PA 1077/131/1 MA 300/01301

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