

Package leaflet: Information for the user

Warticon® 0.15% w/w CREAM Podophyllotoxin

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 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 Warticon Cream is and what it is used for
2. What you need to know before you use Warticon Cream
3. How to use Warticon Cream
4. Possible side effects
5. How to store Warticon Cream
6. Contents of the pack and other 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 or external warts on the vagina in women.

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

Do not use Warticon Cream if:

- you are **allergic** (*hypersensitive*) to podophyllotoxin or any of the other ingredients of Warticon Cream (listed in section 6)
- your warts are on areas of broken/damaged or bleeding skin
- you are already using another medicine containing podophyllotoxin.

Warnings and Precautions

Talk to your doctor or pharmacist before using this medicine if:

- your warts cover an area bigger than 4 centimetres (approximately the size of a postage stamp). You may need to have this medicine applied by a nurse/doctor in a clinic.

Warticon Cream is only to be used on the affected skin. Do not take Warticon Cream by mouth.

Do not apply Warticon Cream to warts on the inside of the penis, vagina or rectum. Warticon Cream should only be applied to warts on the outside (external) skin.

Avoid applying Warticon Cream to healthy skin surrounding the wart.

Avoid getting Warticon Cream in your eyes as it may cause irritation. **If you accidentally get Warticon Cream in your eyes rinse immediately** with plenty of water and see a doctor.

Do not put a dressing (such as a plaster) over the top of the area treated with Warticon Cream.

→ **Check with your doctor** if you think any of these may apply to you.

What to avoid while using Warticon Cream

- It is advisable to **avoid sex** during treatment with Warticon Cream. You should wait until your warts have gone and your skin has healed
- **Genital warts are contagious.** You can give them to, or get them from, a sexual partner.

➔ If you do have sex, you must use a condom to help prevent the spread of genital warts and to protect your partner from coming into contact with podophyllotoxin (since it is irritant).

Other medicines and Warticon Cream

Tell your doctor or pharmacist if you are using any other medicines, have recently used, or might use other medicines. This includes medicines bought without a prescription.

Children

The use of Warticon Cream is not recommended for children under 18 years as use in this age has not been established.

Pregnancy and breast-feeding

Warticon Cream is not recommended for use during pregnancy.

- **Tell your doctor if you are pregnant** or planning to become pregnant
- **Use a reliable method of contraception** to prevent pregnancy, while you are using Warticon Cream
- **If you do become pregnant during treatment** with Warticon Cream, tell your doctor.

Breast-feeding is not recommended during treatment with Warticon Cream. Discuss with your doctor whether you choose to breast-feed or to use podophyllotoxin.

Important information about some of the ingredients in Warticon Cream

Warticon Cream contains butyl hydroxyanisole (E320), sorbic acid, stearyl and cetyl alcohols which may cause local skin reactions (e.g. contact dermatitis). Butyl 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. 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 (every 12 hours) for 3 days.
- Do not apply any cream for the next 4 days. This completes one treatment course.
- When you apply Warticon cream, after two or three days you may notice mild irritation of the areas treated. This shows that Warticon Cream is starting to work. However, Warticon cream can cause severe **skin reactions**. If this occurs, stop using Warticon Cream and seek medical attention. See '*Possible side effects*' in **section 4** for further information.
- 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 gently with a clean towel.
2. Using a fingertip, apply Warticon Cream to cover each wart. Use only enough cream to cover each wart.
3. 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.
4. Wash your hands thoroughly.
5. 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 get Warticon Cream in your mouth, rinse at once with water.
- 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.

If you use more Warticon Cream than you should

If you accidentally use too much cream, wash the cream from the treatment area immediately and see a doctor.

If you forget to use Warticon Cream

Apply Warticon Cream as soon as you remember. If it is nearly time for your next dose, wait until then. **Do not use a double dose** to make up for a forgotten dose.

4. Possible side effects

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

If you experience any of the following serious side effects, stop using Warticon Cream and seek medical attention:

- severe burning, stinging, pain, bleeding, itching or swelling of the treated skin. If these symptoms occur, wash Warticon Cream from your skin with soap and water immediately.

➔ **Contact your doctor as soon as possible.**

Very common side effects

These may affect **more than 1 in 10 people**:

- wearing away of the top layers of skin, application site irritation including redness, itching, burning sensation

Other side effects with frequencies that cannot be estimated from the available data include:

- allergic reaction, pain, swelling, bleeding
- damage to or loss of the top layer of skin, weeping wound
- skin ulcer, scab, skin discoloration, dry skin, blister.

These effects can occur on the area of skin where you use the cream.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie

5. How to store Warticon Cream

- Keep this medicine out of the sight and reach 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.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other 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, triglycerides – medium chain, butyl hydroxyanisole (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.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Phoenix Labs
Suite 12, Bunkilla Plaza,
Bracetown Business Park,
Clonee, County Meath, Ireland

Manufacturer:

Delpharm Bladel BV
Industrieweg 1, 5531 AD Bladel, The Netherlands

OR

Phoenix Healthcare Limited
Unit 31, 2nd Avenue,
Cookstown Industrial Estate,
Dublin 24, D24 TP60,
Ireland

OR

LABORATORI FUNDACIÓ DAU
Pol. Ind. Consorci Zona Franca. c/ C, 12-14
08040 Barcelona
Spain

[Only the site responsible for batch release will be listed on the PIL included in the pack].

Other formats:

If this leaflet is difficult to see or read or you would like it in a different format, please contact:
Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, County Meath, Ireland.

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland: Warticon 0.15% w/w Cream
Spain: Wartec Crema
The Netherlands: Wartec, crème 1,5 mg/g
United Kingdom: Warticon 0.15% w/w Cream

This leaflet was last revised in January 2023.

PL 35104/0023
PA 1113/017/001

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