

Package Leaflet: Information for the user

Pedamed 100mg/g Cutaneous Powder
Zinc undecylenate

Please read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again
- If you need more information or advice, please ask your doctor or pharmacist
- You must contact your doctor if your symptoms get worse or do not improve
- 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 Pedamed Powder is and what it is used for
2. Before you use Pedamed Powder
3. How to use Pedamed Powder
4. Possible side effects
5. How to store Pedamed Powder
6. Further information.

1. What Pedamed 100mg/g Cutaneous Powder is and what it is used for

Pedamed Powder contains the active ingredient zinc undecylenate. Zinc undecylenate is an antifungal which works by preventing fungal growth that can cause skin infections.

Pedamed Powder is used for the treatment and prevention of athlete's foot and other fungal skin infections. It is also used to remove foot odours and to stop feet from sweating.

Pedamed Powder is for use on the skin only.

2. Before you use Pedamed 100mg/g Cutaneous Powder

Do not use Pedamed Powder if you are allergic to zinc undecylenate or to any of the other ingredients listed (see ingredients section).

Take special care with Pedamed Powder if your skin is damaged - do not use it on areas of broken skin.

If any of the above applies, please talk to a doctor or pharmacist before using this medicine.

Taking other medicines:

Always tell your doctor or pharmacist about all the medicines you are taking. This means medicines you have bought yourself as well as those you have on prescription from your doctor.

Pregnancy and breast-feeding:

Please let your doctor or pharmacist know if you are pregnant or breast feeding or planning on getting pregnant. If you become pregnant whilst you are using Pedamed Powder, tell your doctor.

Driving and using machines:

Pedamed Powder does not affect your ability to drive and operate machinery.

3. How to use Pedamed 100mg/g Cutaneous Powder

Read this section carefully to see how to use Pedamed Powder.

If Pedamed Powder has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely:

- Pedamed Powder is for use on the skin only
- Do not get Pedamed Powder in your eyes. Nose or mouth. If you get this medicine in your eyes, nose or mouth, rinse immediately with cool tap water
- Wash your hands before and after using this medicine
- Clean and dry the affected area
- Shake a thin layer of Pedamed Powder over the affected area twice daily and rub the powder in gently. For athlete's foot apply the powder in between the toes and dust socks and inside shoes with powder
- Keep using Pedamed Powder for at least one week after all signs of infection have gone
- For the best results, Pedamed Powder should be used together with an antifungal cream such as Pedamed 100mg/g Cream
- To stop any reoccurrence of the infection, use regularly after showering and bathing.

If Pedamed 100mg/g Cutaneous Powder is used incorrectly:

If anyone accidentally swallows this medicine contact your doctor or go to your hospital casualty department as soon as possible. Take your medicine with you.

If you forget to use Pedamed 100mg/g Cutaneous Powder:

If you forget to use Pedamed Powder don't worry. Apply the powder as soon as possible and then continue the rest of your treatment as usual. Do not apply this powder more than twice daily.

If your symptoms do not go away or you are not sure how to use this medicine and would like further information, then please contact your doctor or pharmacist.

4. Possible side effects

Like all medicines Pedamed Powder may sometimes cause side effects, although not everyone will get them. Skin irritation can occur occasionally when using this product.

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

HPRAs Pharmacovigilance, 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 Pedamed 100mg/g Cutaneous Powder:

Keep out of the reach and sight of children.

Do not store above 25°C. Keep the container tightly closed.

Do not use Pedamed Powder after the expiry date which is stated on the carton and container label after EXP. The expiry date refers to the last day of that month.

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 Pedamed Cutaneous Powder contains

The active substance is zinc undecylenate. Each gram of powder contains 100mg zinc undecylenate equivalent to zinc undecylenate 10%w/w.

The other ingredients are zinc oxide, alum, allantoin, chlorhexidine hydrochloride, levomenthol, talc and maize starch.

What Pedamed Powder looks like and contents of the pack

Pedamed Powder is a fine white cutaneous powder. This medicine is available in a pack size of 65g.

Product Authorisation Holder

Phoenix Healthcare Limited

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

Manufacturer

Ricesteele Manufacturing Limited

Tallaght, Dublin 24, Ireland

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If you would like this leaflet in a different format, please contact the product authorisation holder at the above address.