

## LOGO

### Sodium pyrrolidone carboxylate 2.5% w/w Cream

#### Information for Patients

**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 Sodium pyrrolidone carboxylate 2.5% w/w Cream carefully to get the best results from it.

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

The information in this leaflet has been divided into the following sections:

- 1. Sodium pyrrolidone carboxylate 2.5% w/w Cream is and what it is used for**
- 2. Check before you use Sodium pyrrolidone carboxylate 2.5% w/w Cream**
- 3. How to use Sodium pyrrolidone carboxylate 2.5% w/w Cream**
- 4. Possible side effects**
- 5. How to store Sodium pyrrolidone carboxylate 2.5% w/w Cream**
- 6. Further information**

#### **1. What Sodium pyrrolidone carboxylate 2.5% w/w Cream is and what it is used for**

Sodium pyrrolidone carboxylate 2.5% w/w Cream is a soft, white cream which moisturises the skin.

Sodium pyrrolidone carboxylate 2.5% w/w Cream contains a naturally occurring moisturising agent as well as oils, which prevent moisture loss from the skin. This helps to relieve itch, lubricate and soften the skin.

Sodium pyrrolidone carboxylate 2.5% w/w Cream is used to treat any condition in which dry skin is a feature such as eczema, ichthyosis (hereditary dry skin) and senile pruritus (itching that may occur in old age).

#### **2. Check before you use Sodium pyrrolidone carboxylate 2.5% w/w Cream**

**Do not use Sodium pyrrolidone carboxylate 2.5% w/w Cream:**

- if you are allergic (hypersensitive) to sodium pyrrolidone carboxylate or any of the ingredients of Sodium pyrrolidone carboxylate 2.5% w/w Cream (see section 6 Further information).

If the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you use Sodium pyrrolidone carboxylate 2.5% w/w Cream.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

### **Using other medicines**

Tell your doctor or pharmacist if you are using or have recently used any other medicines which are applied to the skin as they may interfere with Sodium pyrrolidone carboxylate 2.5% w/w Cream.

Other medicines should not be mixed into Sodium pyrrolidone carboxylate 2.5% w/w Cream.

### **Pregnancy and breast-feeding**

It is safe to use Sodium pyrrolidone carboxylate 2.5% w/w Cream if you are pregnant or breast-feeding.

### **Important information about some of the ingredients of Sodium pyrrolidone carboxylate 2.5% w/w Cream**

Sodium pyrrolidone carboxylate 2.5% w/w Cream contains hydroxybenzoates and cetomacrogol emulsifying wax contains cetostearyl alcohol (see section 6 Further information) which may cause allergic reactions (itching, swelling or redness) in some people.

## **3. How to use Sodium pyrrolidone carboxylate 2.5% w/w Cream**

Always use Sodium pyrrolidone carboxylate 2.5% w/w Cream exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

Sodium pyrrolidone carboxylate 2.5% w/w Cream is for cutaneous use. Sodium pyrrolidone carboxylate 2.5% w/w Cream is for external use only and should only be applied to the skin.

**Adults, elderly and children:** Apply liberally to the affected area and massage into the skin. Sodium pyrrolidone carboxylate 2.5% w/w Cream may be used as often as required. It is especially beneficial when used immediately after washing or bathing as the warmth of the skin will increase absorption.

Avoid contact with the eyes, in the event of accidental contact rinse well with water.

If you accidentally swallow some of the cream it is unlikely to cause you any harm.

### **What to do if you use more Sodium pyrrolidone carboxylate 2.5% w/w Cream than you should**

Sodium pyrrolidone carboxylate 2.5% w/w Cream should be applied liberally, so do not worry if you apply more cream than usual.

**If you forget to use Sodium pyrrolidone carboxylate 2.5% w/w Cream**

If you forget to use Sodium pyrrolidone carboxylate 2.5% w/w Cream on any occasion, do not worry, just apply the cream and continue as normal.

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

#### **4. Possible side effects**

If used correctly Sodium pyrrolidone carboxylate 2.5% w/w Cream is unlikely to cause side effects.

Rarely some people may experience an allergic type reaction (e.g. rash) when using Sodium pyrrolidone carboxylate 2.5% w/w Cream.

If your condition worsens consult your doctor or pharmacist.

#### **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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Sodium pyrrolidone carboxylate 2.5% w/w Cream**

Keep out of the reach and sight of children.

Do not use Sodium pyrrolidone carboxylate 2.5% w/w Cream after the expiry date which is stated on the carton, on the base of the tube or on the labelling of the tub. The expiry date refers to the last day of that month after EXP.

Do not store above 25°C. Store in the original container.

Do not use Sodium pyrrolidone carboxylate 2.5% w/w Cream if you notice a change in the colour or feel of the cream.

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

## 6. Further information

### **What is in Sodium pyrrolidone carboxylate 2.5% w/w Cream?**

The active ingredient in this medicine is sodium pyrrolidone carboxylate 2.5% w/w. The other ingredients are liquid paraffin, isopropyl myristate, sodium lactate, cetomacrogol emulsifying wax (containing cetostearyl alcohol and macrogol cetostearyl ether), myristyl myristate, macrogol cetostearyl ether, hydroxybenzoates (parabens): methyl (E218), ethyl (E214), propyl (E216) and butyl parahydroxybenzoates, phenoxyethanol and purified water.

### **What Sodium pyrrolidone carboxylate 2.5% w/w Cream looks like and contents of the pack**

It is a soft, white, oil-in-water cream.

Sodium pyrrolidone carboxylate 2.5% w/w Cream comes in plastic tubes of 50g (grams) and 100g and tubs containing 500g with a pump dispenser.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

The product authorisation holder is: Alliance Pharma (Ireland) Limited, United Drug House, Magna Drive, Dublin, D24 X0CT, Ireland

Sodium pyrrolidone carboxylate 2.5% w/w Cream is manufactured by: Dales Pharmaceuticals Limited, Skipton, North Yorkshire, BD23 2RW UK

The information in this leaflet applies only to Sodium pyrrolidone carboxylate 2.5% w/w Cream. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

**This leaflet was last** revised: July 2019

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