

Patient information leaflet

Clobetasol Propionate, Miconazole Nitrate & Gentamicin Sulphate Cream SONADERM[®]-GM CREAM

Clobetasol Propionate, Miconazole Nitrate & Gentamicin Sulphate Cream

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

In this leaflet:

- a) What Sonaderm-GM Cream is and what it is used for
- b) Before you apply Sonaderm-GM Cream
- c) How to apply Sonaderm-GM Cream
- d) Possible side effects
- e) How to store Sonaderm-GM Cream
- f) Further information

a) WHAT SONADERM-GM CREAM IS AND WHAT IT IS USED FOR

SONADERM-GM Cream contains Clobetasol Propionate (a steroid), Miconazole Nitrate (an antifungal) and Gentamicin Sulphate (an antibiotic).

It is used in the treatment of resistant dermatoses such as refractory eczemas and psoriasis due to bacterial or fungal infection where secondary bacterial or fungal infection is present, suspected or likely to occur.

b) BEFORE YOU APPLY SONADERM-GM CREAM

Do not apply Sonaderm-GM cream:

- If you are allergic to any of the ingredients of this medicine.
- If you have any other skin conditions for which you are on medication, please tell your

doctor, healthcare care provider or pharmacist

Take special care with Sonaderm-GM cream

- This cream should not come in contact with the eyes
- This cream should not be used with an airtight dressing
- It should not be applied on broken or damaged skin or within skin folds.
- If you are using other oral/topical medication containing steroids. Combining Sonaderm-GM cream with these medicines may result in serious infections.
- If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your doctor, healthcare care provider or pharmacist

Taking other medicines

Please tell your doctor, healthcare care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, ask your doctor, healthcare care provider or pharmacist for advice before taking this medicine.

Driving and using machines

There are no serious effect expected to occur with topical use of Sonaderm-GM cream on driving and using machinery.

c) HOW TO APPLY SONADERM-GM CREAM

Always apply Sonaderm-GM cream exactly as your doctor or health care provider has told you. It is usually for adults and children over 2 years for administration to the affected area.

A thin layer of cream should be applied to the affected skin areas twice daily and rubbed gently and completely.

Use in children less than 2 years

SONADERM-GM Cream should not be used in children below 2 years of age.

If you apply more Sonaderm-GM cream then you should

Acute over dosage is very unlikely to occur. However a situation of over dosage or misuse or excessive use can result in skin irritation.

1. Tell your doctor, health care provider, pharmacist or nearest hospital casualty department immediately.
2. Take the container and any remaining tube with you.

If you forget to apply more Sonaderm-GM cream

If you forget to apply Sonaderm-GM cream, then apply it as soon as you remember, but if it is almost time for your next application, skip the missed dose and continue as usual.

Do not over apply to make up for a forgotten dose.

If you stop taking Mefal-Spas tablets

Do not stop taking medicines on your own. Always consult your doctor, health care provider or pharmacist before stopping.

d) POSSIBLE SIDE EFFECTS

Like all medicines, Sonaderm-GM cream can cause side effects, although not everybody gets them.

Seek medical help if you have any local skins reactions such as rash at the site of application which may look like the symptoms of the condition under treatment.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your doctor, healthcare care provider or pharmacist.

e) HOW TO STORE SONADERM-GM CREAM

- Keep out of the reach and sight of children.
- Store below 30°C. Do not freeze.
- For External Use Only
- Do not use Sonaderm-GM cream after the expiry date which is stated on the blister carton/bottle/container after 'Expiry Date'. 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.

f) FURTHER INFORMATION**What Sonaderm-GM cream contains**

The active substances are Clobetasol Propionate, Miconazole Nitrate and Gentamicin Sulphate

The other ingredient(s) are Sodium Acid phosphate, Cetamacrogol 1000, Cetostearyl Alcohol, Liquid Paraffin, White Soft Paraffin, Chlorocresol, Propylene Glycol and Purified Water.

What Sonaderm-GM cream look like and contents of the pack

Sonaderm-GM cream is white to almost white smooth cream with uniform consistency, free from gritty particles & foreign matter.

Sonaderm-GM cream is available in an aluminium collapsible tube of 10 gm.

Name and full address of Marketing Authorization Holder and Manufacturing site:

Marketing Authorization Holder

Blue Cross Laboratories Pvt Ltd.
Peninsula Chambers, Ganpatrao Kadam Marg,
Lower Parel, Mumbai - 400013, Maharashtra, India.

Manufacturing site:

Blue Cross Laboratories Pvt Ltd.
L – 17, Verna Industrial Estate, Verna, GOA – 403 722.

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