

Product Information

Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

1.1 (Invented) Name of the medicinal product

3-Xon Cream (Ketoconazole , Clobetasol Propionate & Neomycin Sulphate Cream)

1.2 Strength

Ketoconazole B.P.	1.0%w/w
Clobetasol Propionate B.P	0.025% w/w
Neomycin Sulphate B.P	5000 IU
Cream Base	Q.S

1.3 Pharmaceutical Form

Cream

2. Qualitative and Quantitative Formula

Batch Size: 100 Kg (3333 Tubes)

Sr. No.	Ingredients	O.A%	Label Claim (%w/w)	Unit Formula (gm/kg)	Batch Formula (Kg)	Functions
Active						
1.	Ketoconazole BP	5%	1.0%	10.5	1.05	Anti fungal
2.	Clobetasol Propionate B.P	5%	0.025%	0.26	0.026	Corticosteroids
3.	Neomycin Sulphate B.P	25%	5000 I.U	0.80625	0.080625	Antibiotics
Excipients						
4.	White soft Paraffin BP	-	-	150.00	15.00	Emollient
5.	Cetostearyl Alcohol BP	-	-	72.00	7.200	Viscosity increasing agent
6.	Cetomacrogol 1000 BP	-	-	18.00	1.800	Ointment base
7.	Light liquid paraffin BP	-	-	35.00	3.500	Lubricant
8.	Chlorocresol BP	-	-	1.000	0.100	Preservative
9.	Propylene Glycol BP	-	-	50.00	5.000	Vehicle
10.	Butylated Hydroxy Toluene BP	-	-	1.000	0.100	Anti oxidant
11.	Purified Water BP	-	-	Q.S to 1.0 kg	Q.S to 100 kg	Vehicle

3. Pharmaceutical form

White coloured smooth cream.

4. Clinical particulars:

4.1 Therapeutic Indication:

3- Xon Cream is used for Inflammatory skin conditions, Fungal infections of superficial skin eg, tinea manus, tinea pedis, tinea corporis, tinea cruris, etc., Itching, Yeast infections of skin, Bacterial infections, Adjunctive therapy in hepatic coma, Preoperative preparation of the bowel and other conditions.

4.2 Posology and method of administration:

Apply an appropriate amount to the affected areas on the skin after cleaning, twice daily. Treatment course: **Tinea corporis and Tinea cruris:** 2 weeks. **Tinea manus and Tinea pedis:** 4 weeks. Or as directed by Physician.

4.3 Contraindications

Hypersensitivity to 3-Xon Cream is a contraindication. In addition, 3-Xon Cream should not be used if you have the following conditions:

- Astemizole
- Cisapride
- Hypersensitivity
- Porphyria
- Preexisting liver disease
- Terfenadine
- Hypersensitivity
- Inflammatory disease
- Intestinal obstruction
- Ulcerative gastrointestinal disease

4.4 Special warnings and precautions for use:

Before using 3-Xon Cream, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Avoid contact with eyes
- Do not use this medicine for diaper rash
- Have or history of hepatic impairment, predisposition to adrenocortical insufficiency
- Limit alcohol consumption
- May interfere with doping tests and sports performance testing
- Pregnant, planning to become pregnant or breastfeeding
- Professional athletes should consult specialist before use
- Take antacid 1 hour before or 2 hours after this drug
- Renal insufficiency
- Do not take by mouth. Consult with your doctor before using this medicine on open wounds, dry, chapped, irritated, or sun-burned skin.
- Wash your hands before and after applying 3-Xon Cream. Clean and dry the skin area to be treated.
- Do not wash the treated area after immediately applying 3-Xon Cream. Also avoid the use of other products on the treated area unless directed by your doctor.
- Applying an excessive amount may result in pilling. Use a thinner layer or lesser quantity of medicine to avoid pilling.
- Avoid getting this medication in your eyes or nose or mouth.

4.5 Interaction with other medicinal products and other forms of interaction

If you use other drugs or over the counter products at the same time, the effects of 3-Xon Cream may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that your doctor can help you prevent or manage drug interactions. 3-Xon Cream may interact with the following drugs and products:

- Abiraterone acetate
- Alcohol
- Alfentanil
- Aliskiren
- Alprazolam
- Aluminium hydroxide and oxide
- Aminoglycosides
- Amphotericin B
- Aprepitant
- Artesunate
- Astemizole
- Beclomethasone
- Bosentan
- Carbamazepine
- Cimetidine
- Cisapride
- Corticotropin
- Coumarin
- Cyclosporin A
- Cyclosporine
- Dabigatran
- Desonide
- Didanosine
- Docetaxel
- Eplerenone
- Erlotinib
- Famotidine
- Fexofenadine
- Flunisolide
- Fluorouracil
- Indinavir
- Methotrexate
- Nephrotoxic drugs
- Neurotoxic drugs
- Oral vitamin B12
- Penicillin V
- Polymyxins
- Prednisone

4.6 Adverse Drug Reactions

The most commonly reported side-effects of 3-Xon Cream are burning of skin, skin rash, irritation, itching of skin, rash, and dryness.

The following is a list of possible side effects that may occur from the use of 3- Xon Cream. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

- Burning of skin
- Skin rash
- Irritation
- Itching of skin
- Rash
- Dryness
- Bleeding
- Indigestion
- Folliculitis
- Numbness
- Vomiting
- Nausea
- Increased tears
- Diarrhoea
- Redness of skin
- Discomfort
- Hair loss
- Skin exfoliation
- Sticky skin
- Application site bleeding
- Hypersensitivity reactions
- Dizziness
- Intolerance to sunlight
- Liver damage
- Prickling
- Tingling
- Enlargement of breasts in men
- Drowsiness
- Inflammation
- Headache
- Menstrual disorders
- Diarrhea

4.7 Fertility, Pregnancy and lactation

Please consult with your doctor for case-specific recommendations.

4.8 Effects on ability to drive and use machines:

If you experience drowsiness, dizziness, hypotension or a headache as side-effects when using 3-Xon Cream medicine then it may not be safe to drive a vehicle or operate heavy machinery. One should not drive a vehicle if using the medicine makes you drowsy, dizzy or lowers your blood-pressure extensively.

4.9 Overdose:

- Do not use more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects. If you suspect that you or anyone else who may have overdosed of 3- Xon Cream, please go to the emergency department of the closest hospital or nursing home. Bring a medicine box, container, or label with you to help doctors with necessary information.

- Do not give your medicines to other people even if you know that they have the same condition or it seems that they may have similar conditions. This may lead to overdosage.
- Please consult your physician or pharmacist or product package for more information.

5. Pharmacological properties

5.1 Pharmacotherapeutic Group

1. Clobetasol

Pharmacotherapeutic group : Corticosteroids, very potent (group IV)

ATC code: D07AD

2. Neomycin Sulphate

Pharmacotherapeutic group : Antibiotics

ATC code: D06AX04

3. Ketoconazole

Pharmacotherapeutic group : Imidazole and triazole derivatives

ATC code: D01AC08

5.2 Pharmacodynamic properties

3- Xon Cream is used for Inflammatory skin conditions, Fungal infections, Itching, Yeast infections of skin, Bacterial infections, Adjunctive therapy in hepatic coma, Preoperative preparation of the bowel and other conditions.

3- Xon Cream is used for Inflammatory skin conditions, Fungal infections, Itching, Yeast infections of skin, Bacterial infections, Adjunctive therapy in hepatic coma, Preoperative preparation of the bowel and other conditions. 3- Xon Cream contains Clobetasol Propionate, Ketoconazole and Neomycin Sulphate as active ingredients.

3- Xon Cream works by preventing yeasts and fungi from reproducing; reducing certain immune responses to reduce redness and itching of the skin; increasing the fecal bile acid excretion.

5.3 Pharmacokinetic properties

Not applicable due to topical administration and direct action on the skin.

5.4 Preclinical safety data

None known.

6. Pharmaceutical particulars

6.1 List of Excipients

Sr.No.	Excipients	Specification
1	White soft Paraffin	BP
2	Cetostearyl Alcohol	BP
3	Cetomacrogol 1000	BP
4	Light Liquid Paraffin	BP
5	Purified Water	BP
6	Chlorocresol	BP
7	Propylene Glycol	BP
8	Butylated Hydroxy Toluene	BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 months from the date of manufacturing.

6.4 Special precautions for storage

Keep in cool and dry place. Protect from light. Keep medicines out of the reach of children.

6.5 Nature and contents of container

30 gm Cream Tube is packed in printed carton along with package insert.

6.6 Special precautions for disposal

No special requirements.

7. REGISTRANT

ONIFAM LABORATORIES LTD

Amori Shopping Plaza,
113 Idimu Road,
Egbeda, P.O. Box 4940,
Ikeja Lagos, Nigeria.

8. DATE OF REVISION OF THE TEXT

9. NAME AND ADDRESS OF MANUFACTURER

YASH MEDICARE PVT.LTD.

Near Sabar Daily, Talod Road,
P.O Hajipur, Tal- Himatnagar, City- Hajipur-383006,
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