

PRODUCT INFORMATION LEAFLET

1. Product Name

Iodex Active Muscle Care

2. Qualitative & Quantitative Composition

Composition (%w/w):

Kundururu (Boswellia serrata Roxb., Exud., Dry Extract) 1.5%,
Nilgiri Tail (Eucalyptus globulus, Lf., Oil.) 1%,
Katuvira (Capsicum minimum, Dried pods, Dry extract) 0.02%,
Karpura (Camphor, powder) 3%; in cream base.

Preservative: Phenoxyethanol.

3. Dosage Form

Soft cream

4. Clinical Particulars

4.1. Uses/Application

Apply sufficient quantity on affected area 3 to 4 times a day for relief from muscle stiffness , backache, neck & shoulder pain and joint pain.

4.2. Posology and method of administration

For external use only.

For use in adults and children aged 12 years and above.

Apply sufficient quantity on affected area 3 to 4 times a day.

After application:

- the hands should be wiped with e.g. an absorbent paper, and then washed, unless they are the site being treated.
- Wait until the product dries before showering, bathing.

4.3. Contra-indications

Do not use this product if:

- You are allergic to Kundururu, Karpura ,Nilgiri Tail, Katuvira or any other

ingredients of this product.

4.4. Warnings and Precautions

Check with your doctor before use if you are allergic to non-steroidal anti-inflammatory medicines used to treat pain, fever or inflammation, such as ibuprofen or aspirin or you have wheezing or shortness of breath or nasal polyps.

Discontinue the treatment if a skin rash develops after applying the product.

Keep out of the sight and reach of children.

Do not give this product to children under 12 years of age, unless prescribed by a doctor. Fits (seizures) may occur due to presence of eucalyptus oil in children with history of fits. In children below 30 months eucalyptus oil may induce spasm of the muscles around the voice box, causing choking.

Do not use on open wounds or damaged skin with occlusive dressings or bandage or a heating pad. Be careful not to get this product in your eyes, nostrils and mouth or swallow it. If any of this happens, rinse well with water. See your doctor if any discomfort.

Do not use with heating pad.

Do not use with occlusive dressings or bandage.

Do not apply more than a thin layer, using only enough to cover the affected area where you have pain.

If the pain does not improve within 7 days, or it gets worse, consult your doctor.

4.5. Interaction with other medicaments and other forms of interaction

Check with your doctor before use if:

you are taking medicines used to prevent blood-clotting ("blood thinners", anticoagulants and antiplatelet drugs) as it may result in increased risk of bleeding.

4.6. Pregnancy and lactation

Check with your doctor before use if:

- you are pregnant, think you may be pregnant.
- you are breast-feeding.

4.7. Effects on ability to drive and use machines, if contra-indicated

Not applicable

4.8. Undesirable effects/side effects

With use of this product, you may develop:

Application site hypersensitivity/reaction; skin burning sensation, rash, itching.

4.9. Overdosing

Consult your doctor immediately if you apply the medicine more than you should or if you swallow this product.

In case of overdose, you may also contact the National Poisons Information Centre of India (24*7).

Details of the same are as below: Department of Pharmacology
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5. Pharmacological

Karpura (Synthetic) – Synthetic Camphor are similar to natural camphor. It provides relief from spasms and cramps, It helps to heal muscular pains and aches.

Kundururu consist of exudate of *Boswellia serrata*. Kunduru exhibits potent anti-inflammatory effects by inhibiting the production of pro-inflammatory cytokines which help in reducing inflammation.

Katuvira is likely to inhibit pro-inflammatory cytokines and enzymes involved in the inflammatory pathway, reducing inflammation and associated pain. Its analgesic action mediated through inhibition of cyclooxygenase enzymes and prostaglandin synthesis, which are responsible for the sensation of pain and inflammation.

The analgesic effects of β -pinene (in Niligiri Taila/eucalyptus oil) occurs via mu-opioid receptors; however, 1,8-cineole (in eucalyptus oil) has been demonstrated to elicit this effect via a mechanism that is independent of the mu-opioid receptor. An alternative mechanism of action for the analgesic effect of 1,8-cineole has been suggested to act through indirect depolarisation of neurons.

6. Pharmaceutical Particulars

6.1. List of Excipients

Light Liquid Paraffin
Iso propyl alcohol

Glycerol monostearate
Emulgade 165#
Phenoxyethanol
Triethanol amine
Biopol 940 (Carbomer 940)
Purified Water

6.2. Incompatibilities

Not applicable

6.3. Shelf life

24 months from the date of manufacturing.

6.4. Special storage conditions

Store at ambient room temperature, avoid excessive heat.

6.5. Nature and specification of the container

Jar with top opening.

6.6. Instructions for Use and Handling

For External Use Only

6.7. Manufacturing License Holder

Refer pack details on manufacturing license holder

6.8. Marketed By

GlaxoSmithKline Asia Private Limited, Patiala Road, Nabha- 147201, Punjab, India

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