

PRODUCT INFORMATION LEAFLET

1. Product Name

Iodex* Balm

2. Qualitative & Quantitative Composition

Active ingredients:

Gandhapura Patra Taila	20 % w/v
Niligiri Taila.....	4% w/v
Tarpin Taila.....	4%w/v
Peppermint Satva	3% w/v
Lavanga Taila.....	0.10% w/v

3. Dosage Form

Topical Ointment

4. Clinical Particulars

4.1. Uses/Application

Massage on affected area for Simple Backache, Neck Pain, Strains & Sprains, Joint Pain.

4.2. Posology and method of administration

For topical use only.

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

Apply a thin layer of the product onto the skin 3 to 4 times per day, where you have pain.

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 Gandhapura Patra Taila, Niligiri Taila, Tarpin Taila Peppermint Satva, Lavanga Taila 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 if the product is used 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 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 overdosage, you may also contact the National Poisons Information Centre of India (24*7).

Details of the same are as below: Department of Pharmacology
All India Institute of Medical Sciences New Delhi-110029
Toll Free No. - 1800 116 117
Tel No.- 26589391, 26593677

5. Pharmacological

Gandhapura Patra Taila/Methyl salicylate is a salicylic acid derivative that is an irritant to the skin and is used topically in counter-irritant preparations.

Menthol: The anti-pruritic and/or analgesic action of menthol is thought to be via transient receptor potential melastatin 8 (TRPM8) activation and/or inhibition of nociceptive sensing TRPA1. Anti-pruritic and/or analgesic activity may be due to menthol's direct activation of Ca²⁺ currents.

Peppermint Satva /Menthol has a cooling-anesthetising effect when applied to the skin. The topical application of menthol to the skin is commonly associated with a cooling sensation (by activation of TRPM8), which may control itching.

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.

Lavanga Taila/Clove oil, the mechanism of analgesic action is reported to involve targeting of the sodium, calcium, and chloride channels.

Tarpin Taila /Turpentine oil, possible inhibition of both peripheral and central mechanism (i.e., acting as a narcotic analgesic) has also been suggested as its mechanism of action.

6. Pharmaceutical Particulars

6.1.List of Excipients

Ointment base

Color: Chlorophyll (Spinacia oleracea, Lf. Ext.)

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

Labelled Semi permeable polypropylene (PP) container with PP screw cap.

6.6.Instructions for Use and Handling

For External Use Only

6.7.Manufacturing License Holder

Makson Healthcare Pvt. Ltd.,
182-183, Annaram Village,
Gummadidala Mandal Sangareddy District,
Telangana State- 502313

6.8.Marked By

GlaxoSmithKline Pharmaceuticals Limited,
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