SUMMARY OF PRODUCT CHARACTERISTICS

1-Name of the Medicinal Product :

1.1 Product Name

2 Ultimax Cream

2.1 Strength of Active Ingredients

Methyl Salicylate	25.5 % w/w
Eucalyptus Oil	10.0% w/w
Menthol	3.3% w/w

1.3 Pharmaceutical Dosage Form

Cream

2-Quality and Quantitative Composition :

2.1 Qualitative Declaration

Name of Ingredient	%w/w	Reference monograph	Function
Menthol	3.30	USP	Active
Methyl Salicylate	25.50	BP	Active
Eucalyptus Oil	10.00	JP	Active
Carbopol 934	1.00	BP	Viscosity increasing agent
Polysorbate 80	3.10	BP	Emulsifying Agent
Capsicum Oleoresin	0.50	In-house	Irritant
Chlorophyll Oil Soluble	0.20	In-house	Coloring agent
Triethanolamine	2.00	USP	Alkalizing agent
Chlorocresol	0.10	BP	Antimicrobial preservative
Methyl Hydroxybenzoate	0.10	BP	Antimicrobial preservative
Propyl Hydroxybenzoate	0.01	BP	Antimicrobial preservative
Purified Water	54.19	USP	Solvent

** & *** kindly refer to the calculation of the quantity required

2.2 Quantitative Declaration

Refer to Section 2.1 (Qualitative Declaration)

3-Pharmaceutical Form :

Pale green opaque cream

4-Clinical Particulars

4.1 Therapeutic indications

For temporary relief of pain associated with musculoskeletal soreness and discomfort.

4.2 Posology and method of administration

For topical use only

Gentle massage on intact skin two to three times a day.

Note : The information given here is limited. For further information consult your doctor or pharmacist.

4.3 Contraindications

None known

4.4 Special warning and precautions for use

Warning

This product is contraindicated in infants under 2 years of age. Caution must be exercised when older children are treated. This product contains methyl salicylate and when applied or rub on to the skin, can be absorbed through the skin into the blood. For patients taking warfarin, excessive application to the skin muscle or joint pains may increase the chances of bleeding.

Precautions

- It should not be applied to broken or inflamed skin or near the eyes or mucous membranes.
- For external use only.

4.5 Interaction with other medicinal products and other forms of Interactions

None known

4.6 Pregnancy and lactation

None known

4.7 Effects on ability to drive and use machine

Not applicable.

4.8 Undesirable effects

Hypersensitivity reactions, urticaria and angioneurotic oedema may occur in susceptible persons.

4.9 Overdose and special antidotes.

None known

5-Pharmacological Properties :

5.1 Pharmacodynamic Properties

Ultimax is used for its local action as a rubefacient-counterirritant analgesic when rubbed on the skin.

5.2 Pharmacokinetic Properties

Absorption of methyl salicylate can occur through the skin.

5.3 Preclinical safety Data

NOT AVAILABLE

6-Pharmaceutical Particulars :

6.1 List of excipients

Carbopol 934
Polysorbate 80
Capsicum Oleoresin
Chlorophyll Oil Soluble
Triethanolamine
Chlorocresol
Methyl Hydroxybenzoate
Propyl Hydroxybenzoate
Purified Water

6.2 Incompatibilities

NOT APPLICABLE

6.3 Shelf life

3 years from date of manufacture.

6.4 Special precautions for storage

Store below 30°C. Protect from light and freezing.

6.5 Nature and contents of container

Immediate Container/Packaging

Primary Packaging

Laminated Tube

Description	:	White laminated tube externally preprinted and cap with 15 mm flower pot design white screw cap
Material of Construction	:	LLDPE 1005 / White Copolymer 605 / Aluminium foil 205 / Copolymer 355 / LLDPE 705

Secondary Packaging Components

Outer Container/Packaging
Type: Ultimax unit box
Material: Carton

7-Marketing Authorization Holder :

Name	:	HOVID Bhd.
Address	:	121, Jalan Tunku Abdul Rahman, (Jalan Kuala Kangsar) 30010 Ipoh, Perak, Malaysia

8-Manufacturer Name :

Name	:	HOVID Bhd.
Address	:	121, Jalan Tunku Abdul Rahman, (Jalan Kuala Kangsar) 30010 Ipoh, Perak, Malaysia

9-Date of first authorization/renewal of the authorization :

July 2019 – July 2024

10-Date of revision of the text :

May 2024