SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINALPRODUCT

Afradin Drops

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each 1ml contains 1mg of Dimentidene Maleate.

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

Drops.
A clear, colourless liquid.

4. Clinical particulars

4.1 Therapeutic indications

Afradin Drops is indicated in the case of:

- Allergic skin conditions: itching due to various causes (except for Itching due to Jaundice) eczema and other skin condition causing itching, urticaria, itching associated with diseases that cause rashes and/or spots such as chicken pox; insect bites.
- Allergic conditions involving the upper respiratory tract such as hay fever and other allergic rhinitis such as a running nose, watering eyes and sneezing.
- The treatment of symptoms caused by food and drug allergies.

4.2 Posology and method of administration

Posology

Drops: 20 drops (1ml) = 1mg dimetindene maleate.

Adults and children over 12 years old: 20 to 40 drops (1-2ml) 3 times daily.

Children daily doses from one month to 12 years:

Age	Drops 1 mg / ml
1 month- 1 year	3-10 drops (0.2-0.5ml) 3 times daily
1-3 years	10-15 drops (0.5-1ml) 3 times daily
3-12 years	15-20 drops (0.8-1ml) 3 times daily

Method of administration

For oral administration.

4.3 Contraindications

Afradin Drops must not be used in newborn babies less than1 month old, especially premature babies.

4.4 Special warnings and precautions for use

Afradin drops should be used with caution in patients suffering from glaucoma, Urinary retention (for example prostatic hypertrophy), Chronic obstructive pulmonary disease

4.5 nteraction with other medicinal products and other forms of interaction

The pyridoxine hydrochloride may reduce the effectiveness of levodopa

4.6 Pregnancy and Lactation

Afradin should not be taken in pregnancy or breastfeeding. Unless your doctor has prescribed it for you.

4.7 Effects on ability to drive and use machines

The use of Dimetindene can lead to a drop in concentration; caution is Vital when driving a vehicle or carrying out tasks which requiring concentration for example operating machinery).

4.8 Undesirable effects

Drowsiness especially at the start of treatment. Dryness of the mouth or throat, nausea, dizziness, agitation, headache may sometimes occur. In certain exceptional cases, skin rash and or swelling might be observed, stop treatment and consult your doctor or pharmacist.

4.9 Overdose

overdosage can produce the following symptoms: CNS depression accompanied by drowsiness (especially in adults), CNS stimulation and antimuscarinic effects (especially in children) including the following: excitation, ataxia, hallucinations, tonic or clonic spasms, mydriasis, dryness of the mouth, redness of the face, urine retention, fever and tachycardia. Blood hypotension is also possible. In its terminal phase, coma can be aggravated by cardiorespiratory colapse and death. There has been no report of a fatal outcome of Dimethindene overdosage.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Dimetindene counteracts the effects of histamine, a substance released during allergic Reactions.
Dimetindene occur as a racemic mixture. The (S)-(+)- dimetindene is a potent M2-selective muscarinic receptor antagonist (with lower affinity for M1,M3,and M4 muscarinic receptors).The (R)-(-)- enantiomer is the eutomer(responsible for bioactivity) forhistamine H1 receptor binding.

Mechanism of Action

Dimetindene is a selective histamine H1 antagonist and binds to the histamine H1 receptor. This blocks the action of endogenous histamine,which subsequently leads to temporary relief of the negative symptoms brought on by histamine.

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction

6. PHARMACEUTICALPARTICULARS

6.1 List of excipients

Propylene Glycol
Methyl paraben
Propyl paraben
Citric acid monohydrate
Sodium citrate
Sodium saccharin
Peach Flavour

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

30ml amber glass bottle.

6.6 Special precautions for disposal

No special requirements

7 APPLICANT/MANUFACTURER

Afrab Chem Limited
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