Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Belladonna 0.25% w/w Medicated Plaster

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Belladonna Alkaloids (as Hyoscyamine) 0.25% w/w.
Also contains Lanolin 19.7% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated Plaster
An evenly perforated plaster consisting of a white cloth coated with a medicated adhesive, faced with a white silicon paper and packed in a sealed printed pack.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of muscle pains associated with strains and similar conditions of mild muscle injury.

4.2 Posology and method of administration

One plaster to be applied over the affected area as required. Plaster to be removed after 2 – 3 days. Apply another plaster if required.
Children: Not recommended for use by children under 10 years of age.

4.3 Contraindications

Do not use if you suffer from Glaucoma.
Do not use if you are allergic to adhesive plasters.
Do not use if you are using a medication that contains antihistamines.

4.4 Special warnings and precautions for use

1. Occasional local irritation may occur while using this product.
2. If the skin beneath the plaster begins to hurt, remove the plaster immediately and wash with soap and water.
3. If symptoms persist consult your doctor.
4. Keep out of the sight and reach of children.
5. Report any unwanted effects to your doctor or pharmacist.
6. Do not use if you have inflamed or broken skin.
7. Do not use if you have applied any other medication to the skin.
8. Contains lanolin - may cause local skin reactions (e.g. contact dermatitis)

4.5 Interaction with other medicinal products and other forms of interaction

1. The plaster should not be applied over other medication which has been applied to the skin as there is the potential for occlusion which may affect the action of the other medication.
2. Atropine is an antimuscarinic and may be absorbed. It has the potential for interacting with other drugs having a similar affect such as antihistamines.

4.6 Fertility, pregnancy and lactation

Not recommended for use by pregnant women, nursing mothers. Systemic dosing, (oral, SC etc) of Atropine is contra-indicated in pregnant and lactating women. Systemic absorption of active from the topical patch is not measurable.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

May cause local irritation.

4.9 Overdose

Over dosage from adhesive plaster is rare. If over dosage does occur it should be treated as for Atropine poisoning.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Atropine is an antimuscarinic alkaloid with both peripheral and central actions.

5.2 Pharmacokinetic properties

There is minimal systemic absorption of Atropine from a self-adhesive plaster applied to the skin.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Adhesive base
Lanolin
Pale Crepe Rubber
Partially hydrogenated wood resins
Corn Starch
Kaolin
2,5, di-tert-amylhydroquinone

Plaster
Flannelette

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.
See section 4.2 for in-use information.

6.4 Special precautions for storage

Do not store above 25°C. Keep away from sources of direct heat.

Store in the original package to protect from light.

6.5 Nature and contents of container

28cm × 17.5cm plaster in a bag.
or
19cm x 12.5cm plaster in a bag.
or
12.5cm x 9.5cm plaster in a bag.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Cuxson Gerrard Healthcare Limited
Unit 3d North Point House
North Point Business Park
New Mallow Road
Cork
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23188/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1 April 1983

Date of last renewal: 1 April 2008

10 DATE OF REVISION OF THE TEXT

May 2023