SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

BELLADONNA PLASTER

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Belladonna Alkaloids (as Hyoscamine) 0.25% w/w

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Medicated adhesive plaster, containing Belladonna Alkaloids in the adhesive mass.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of aches and pains, such as - muscular tension and strain, stiff neck and aching shoulders, sciatica, lumbago, rheumatism, backache.

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 on the face. 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 special precautions for use

Occasionally local irritation may occur while using this product.

If the skin beneath the plaster begins to hurt, remove the plaster immediately and wash with soap and water.

If symptoms persist consult your doctor.

Keep out of the reach of children.

Report any unwanted effects to your doctor or pharmacist.

Do not use if you have inflamed or broken skin.

Do not use if you have applied any other medication to the skin.

4.5 Interaction with other medicinal products and other forms of interaction

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.

Atropine is an antimuscarinic and may be absorbed. It has the potential for interacting with other drugs having similar affect such as antihistamines.

4.6 Fertility, pregnancy and lactation

The plaster is not recommended for use during pregnancy or breast-feeding.
Systemic dosing, (oral, SC et) 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 relevant.

4.8 Undesirable effects

May cause local irritation (Very rare, <1/10,000).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Belladonna alkaloids, tertiary amines ATC Code: A03BA
Atropine is an antimuscarinic alkaloid with both peripheral and central actions.
When applied topically Atropine is transported to the affected area where it desensitises the nerve endings associated with the pain response.

5.2 Pharmacokinetic properties

There is minimal systemic absorption of Atropine from a dermal patch.

Atropine is rapidly cleared from the blood and is excreted in the urine as Hepatic Metabolites and unchanged drug.

The mean half life of an IV injection is 4 hours.

5.3 Preclinical safety data

None

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

A pressure sensitive adhesive base containing - Lanolin BP, Natural Rubber, Partly Hydrogenated Wood Resins, Corn Starch, Kaolin, 2,5 di-tert-amylhydroquinone.

6.2 Incompatibilities

Not known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25ºC. Store in original package.

Keep away from sources of direct heat and sunlight.

6.5 Nature and contents of container

Each plaster is packed in a polypropylene/metallised polypropylene laminate bag.

Pack sizes:
2 individually wrapped plasters of 9.5 x 12.5 cm in an outer carton
1 wrapped plaster of 28 x 17.5 cm

6.6 Special precautions for disposal

No special requirements for disposal.

7. MARKETING AUTHORISATION HOLDER

Cuxson Gerrard & Co. Ltd
125 Broadwell Road
Oldbury
West Midlands.
B69 4BF

8. MARKETING AUTHORISATION NUMBER

PL 00089/50013R.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/02/2011

10 DATE OF REVISION OF THE TEXT

15/11/2016