SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cinnarizine 15mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains cinnarizine 15mg

Excipient(s) with known effect
Each tablet contains 170 mg lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White flat, bevelled-edged tablets, about 9 mm in diameter, coded 'CNZ 15' with breakline on one side, twin triangle logo on reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Cinnarizine is used for the control of vestibular disorder such as vertigo, tinnitus, nausea and vomiting as seen in Meniere's disease. Cinnarizine is also effective in the control of motion sickness.

4.2 Posology and method of administration

Cinnarizine is for oral administration to both adults and children according to the following dosage regimen:

VESTIBULAR SYMPTOMS

Adults and Children over 12 years:

2 tablets three times a day

Children 5-12 years:

Half the adult dose

MOTION SICKNESS

Adults and Children over 12 years:

2 tablets 2 hours before travel and 1 tablet every 8 hours during journey if necessary.

Children 5-12 years:

Half the adult dose

Route of Administration

Oral

4.3 Contraindications

Contra-indicated in porphyria and in patients with known hypersensitivity to cinnarizine.

4.4 Special warnings and precautions for use

As with other antihistamines, cinnarizine may cause epigastric discomfort; taking it after meals may diminish gastric irritation. Cinnarizine should only be given to patients with Parkinson's disease if the advantages outweigh the possible risk of aggravating this disease.

4.5 Interaction with other medicinal products and other forms of interactions

Concurrent use of alcohol, CNS depressants or tricyclic antidepressants may potentiate the sedative effects of these of these drugs, or cinnarizine.

The antihistamine effect of cinnarizine may prevent an otherwise positive reaction to dermal reactivity indicators if used within 4 days prior to skin testing.

4.6 Pregnancy and lactation

The safety of cinnarizine in human pregnancy has not been established although studies in animals have not demonstrated teratogenic effects. As with other drugs, it is not advisable to administer cinnarizine in pregnancy.

There are no data on the excretion of cinnarizine in human breast milk and its use in nursing mothers is not recommended.

4.7 Effects on ability to drive and use machines

Cinnarizine may cause drowsiness; patients affected in this way should not drive or operate machinery. Avoid alcoholic drink.

4.8 Undesirable effects

Drowsiness and gastro-intestinal disturbances may occur. These are usually transient. In rare cases, headache, dry mouth, weight gain, perspiration or allergic reactions may occur. Very rare cases of lichen planus, lupus-like skin reactions and cholestatic jaundice have been reported.

Rare cases of aggravation or appearance of extrapyramidal symptoms (sometimes associated with depressive feelings) have been described, predominantly in elderly people during prolonged therapy. The treatment should be discontinued in such cases.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Vomiting, drowsiness, coma, tremor and hypotonia may occur. There is no specific antidote to cinnarizine and in the event of overdosage, gastric lavage is recommended. The administration of activated charcoal may help to reduce absorption of cinnarizine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cinnarizine is a piperazine derivative with the actions and uses of the antihistamines; it also inhibits the transport of calcium ions across cell membranes. It is mainly used for the symptomatic treatment of nausea and vertigo due to Meniere's disease and other labyrinthine disturbances and for the prevention and treatment of motion sickness. Cinnarizine is reported to possess smooth muscle relaxant properties and to inhibit vasoconstriction, and is thus used in the management of various vascular disorders. Sedative effects are not marked.

5.2 Pharmacokinetic properties

In general, antihistamines are readily absorbed from the gastro-intestinal tract, metabolised in the liver and excreted usually mainly as metabolites in the urine.

5.3 Preclinical safety data

None available

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Lactose

Maize Starch

Povidone

Magnesium Stearate

Pregelatinised Starch

Colloidal anhydrous silica

6.2 Incompatibilities

None known

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25ºC.

6.5 Nature and contents of container

Polypropylene tubular container with an open end equipped to accept a polyethylene closure with tamper evident tear strip containing 7, 10, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 250, 500 or 1000 tablets.

PVdC coated PVC/Aluminium blisters (60g/m^2 PVdC on 250µm PVC/20µm A1) containing 7, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 112 or 120 tablets.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Teva UK Limited,
Ridings Point, Whistler Drive,
Castleford,
WF10 5HX,
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PL 00289/1440

9 DATE OF THE FIRST AUTHORISATION OR RENEWAL

Granted: 02.11.84
Renewed: 02.11.89
Renewed: 12.12.95
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10 DATE OF REVISION OF THE TEXT

18/10/2021