Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zynor 10mg Film coated Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains cetirizine dihydrochloride 10 mg.

Also contains 100 mg Lactose (as monohydrate).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablets.

White circular film coated tablets with ‘CTZ 10’ embossed on one side and with a breakline on the other side.

The scoreline on the tablet is only to facilitate the ease of breaking or swallowing and not to divide in equal doses’ the tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of seasonal and perennial allergic rhinitis, urticaria, senile pruritus.

4.2 Posology and method of administration

Oral administration.

Adults and children aged over 12 years
Usual dose is 10 mg daily to be given in the evening.

Patients with renal problems
Dosage should be reduced to 5 mg daily.

The dosage should be halved and taken twice daily for patients who experience mild side-effects.

4.3 Contraindications

Zynor 10mg Tablets are contraindicated in patients with a history of hypersensitivity to any of the constituents.

4.4 Special warnings and precautions for use

1. The side effects reported include headache, dizziness, dry mouth and sedation and in some patients, reversible changes in liver function may occur. For those affected the usual dosage should be halved and taken twice daily.

2. The dosage should be reduced and drug used with caution in patients with significant renal impairment.

3. For patients with decreased hepatic function, the drug should be reduced and used with caution.

The tablets also contain lactose monohydrate. The patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

No potentiation was demonstrated in concomitant use of the drug with alcohol at a blood level of 0.8 g/L and diazepam at therapeutic doses. However, usual cautions should be maintained in case of CNS depressants as there is a lack of sufficient experience which is required for the necessary evaluation of the potential risk.

4.6 Pregnancy and lactation

There is no experience of use during human pregnancy and animal studies did not show a teratogenic effect. The drug is excreted in breast milk, therefore, use of cetirizine should be avoided during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

In clinical studies, cetirizine was shown to be usually non-sedative, therefore, should not interfere with activities requiring mental alertness, such as operating machinery or driving. However, in some sensitive people (which is less than 10%) who might experience drowsiness, they should not drive or operate machinery unless it has been shown not to interfere with their physical and mental capacity. This effect is minimised by administration of ½ the recommended dose twice daily.

4.8 Undesirable effects

The side effects reported include headache, dizziness, dry mouth and sedation and in some patients, reversible changes in liver function may occur. For those affected the usual dosage should be halved and taken twice daily.

4.9 Overdose

Drowsiness may be a symptom of overdose. This can happen due to administration of 50 mg of cetirizine dihydrochloride as one dose. Gastric lavage should be performed together, along with the usual supportive measures should massive overdosage occur. To date there is no specific antidote.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cetirizine is a potent antihistamine possessing a low potential for drowsiness at pharmacological active doses with additional anti-allergic properties. Cetirizine is a selective H_1 antagonist with negligible effects on other receptors, therefore, is virtually free from anti-cholinergic and anti-serotonin effects. Cetirizine inhibits the histamine mediated during ‘early' phase of the allergic reaction and also reduces the migration of inflammatory cells and the release of mediators associated with the ‘late' allergic response.

5.2 Pharmacokinetic properties

Cetirizine is well absorbed after oral administration. It is highly bound to plasma protein (over 90%), with a $T_{1/2}$ of 9-12 hours. Cetirizine is metabolised in part in the liver and excreted via the urine.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Starch
Magnesium Stearate
Opadry Y-1-7000 *which contains:*
Hypromellose
Titanium dioxide (E171)
Macrogol (PEG 400)

6.2 Incompatibilities

Not Applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25^{o}C. Store in the original package.

6.5 Nature and contents of container

The tablets are packed in clear PVC/aluminium foil blister strips and are available in pack sizes of 10, 15, 20, 30, 50 and 100 tablets. Not all pack sizes may be marketed.

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.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 0282/075/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th August 2001

Date of last renewal: 24th August 2006

10 DATE OF REVISION OF THE TEXT

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