SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

[Invented name], 2 mg/ml, syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of syrup contains 2 mg fenspiride hydrochloride (*Fenspiridi hydrochloridum*).

Excipients with known effect: sucrose, methyl parahydroxybenzoate, propyl parahydroxybenzoate, sunset yellow, glycerol.
5 ml of syrup contains 3 g sucrose (corresponding to 0.25 bread units).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.
Orange, clear syrup with the honey flavor.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of (cough and expectoration) in the course of inflammatory diseases of the bronchi and lungs.

Note: these may not delay the initiation of treatment with antibiotics if necessary.

4.2 Posology and method of administration

For oral use.
The package comes with a measuring spoon or an oral syringe. Measuring spoon or a measure should be stored together with a bottle containing the syrup in the original package.

Children over 2 years: 4 mg/kg body weight/day, i.e.:

- weighing less than 10 kg: 10 to 20 ml of syrup daily in divided doses;
- weighing more than 10 kg: 30 to 60 ml of syrup daily in divided doses.

Adults: 45 to 90 ml of syrup daily in divided doses.

The syrup should be administered directly before meals.

5 ml of syrup contains 10 mg of fenspiride hydrochloride, and 3 g of sucrose (corresponding to 0.25 bread units).

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Do not use in children below 2 years of age.

4.4 Special warnings and precautions for use

Therapy with fenspiride does not replace the treatment with antibiotics.

Medicinal product [Invented name] contains preservatives - methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

Medicinal product [Invented name] contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucosegalactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

5 ml of syrup contains 3 g of sucrose. This should be taken into account in patients with diabetes mellitus.

Medicinal product [Invented name] contains sunset yellow, which may cause allergic reactions.

Medicinal product [Invented name] contains glycerol, which can cause headache, stomach upset and diarrhea.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions between fenspiride and other drugs.
However, due to the antihistaminic activity of fenspiride, interactions can be expected with:

- barbiturates,
- other antihistamines,
- analgesics (including opioid analgesics),
- sedative drugs,
- MAO inhibitors,
- alcohol.

4.6 Fertility, pregnancy and lactation

Cases of cleft palate in fetuses were observed in the animal studies, in two species (rats and rabbits). There are currently no clinical data on the possibility of fenspiride foetotoxicity or fetal malformations when the medicine is administered during pregnancy. For this reason it is not recommended to use the medicine during pregnancy.

There are no data on the excretion of fenspiride into breast milk, however it is not recommended to use the medicine during breast-feeding.

4.7 Effects on ability to drive and use machines

[Invented name] may impair ability to drive, use machines and psychomotor performance, therefore patient should be informed about this when starting therapy.

4.8 Undesirable effects

Adverse reactions listed below are classified according to frequency and system organ class.
Frequency categories are defined according to the following convention:
Very common: ≥ 1/10,
Common: ≥ 1/100 to < 1/10,
Uncommon: ≥ 1/1000 to < 1/100,
Rare: ≥ 1/10 000 to < 1/1000,
Very rare: < 1/10 000,
Not known (frequency cannot be estimated from the available data).

Cardiac disorders:
Rare: moderate tachycardia, reversible upon reduction of the dose.

Gastrointestinal disorders:
Frequency not known: stomach and intestines dysfunction, nausea, upper abdominal pain.

Nervous system disorders:
Rare: headache.
Frequency not known: somnolence.

Immune system disorders:
Rare: rash, erythema, urticaria, Quincke's edema, erythema perstans.

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 national reporting system listed in Appendix V*.

4.9 Overdose

In case of overdose, following symptoms may occur:
- drowsiness or agitation,
- nausea, vomiting,
- tachycardia.

Gastric lavage and cardiac monitoring must be performed.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other systemic drugs for obstructive airway diseases, ATC code: R 03 DX 03.

Fenspiride has an anti-inflammatory and bronchodilator activity. These properties are most likely due to several concomitant mechanisms of action, such as:
- antagonistic effect on histamine H_1 receptors and papaverine like spasmolytic effect (or musculo tropic);
- anti-inflammatory effect which may result from the reduced secretion of inflammatory mediators (cytokines, TNF-α, arachidonic acid derivatives, free radicals).

5.2 Pharmacokinetic properties

The plasma peak concentration after oral administration of fenspiride is reached within an average of 2.3 ± 2.5 hours. The half-life is approximately 12 hours. Fenspiride is primarily eliminated via kidneys.

5.3 Preclinical safety data

There are no adequate non-clinical data on the safety of the medicine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)

Potassium sorbate (E202)
Glycerol
Saccharin sodium (E945)
Sucrose
Vanilla flavouring:
    Main components:
    Flavouring components
    Propylene glycol
Honey flavouring:
    Main components:
    Flavouring substance(s)
    Flavouring preparation(s)
    Propylene glycol
    Sodium citrate (E331)
Sunset yellow (E110)
Citric acid monohydrate
Water, purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
Shelf life after first opening of the bottle: 6 months.

6.4 Special precautions for storage

Do not store above 25ºC. Do not refrigerate or freeze.

6.5 Nature and contents of container

Brown PET bottle containing 150 ml of Fenspiride hydrochloride 2 mg/ml, syrup – closed by a white polyethylene (HDPE) screw cap with tamper-evident security ring and liner inside. The liner is made of expanded polyethylene coextruded between two strips of solid polyethylene.

The labeled bottle, together with a package leaflet: information for the user and 5 ml measuring spoon are packed into a unit carton. The measuring spoon is made of colourless polystyrene. It has the lines at: 1.25 ml, 2.5 ml and 5 ml.
or
The labeled bottle, together with a package leaflet: information for the user and 10 ml oral syringe are packed into a unit carton. The oral syringe is made of colourless polyethylene LDPE and white polystyrene. The dosing plastic pipette is scaled from 0 to 10 ml with 0.5 ml graduation.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7. MARKETING AUTHORISATION HOLDER

Medana Pharma SA
ul. Władysława Łokietka 10
98-200 Sieradz

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT