1. NAME OF THE MEDICINAL PRODUCT

SEKISAN Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of syrup contains:

Cloperastine fendizoate ..... 3.54 mg
(equivalent to 2 mg of cloperastine hydrochloride)

Excipient with known effect: 450 mg of Sucrose (450 mg), 1.22 mg of methyl parahydroxybenzoate (E-218), 0.18 mg of propyl parahydroxybenzoate (E-216).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

White opaque suspension with a characteristic banana flavour aroma.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

SEKISAN Syrup is indicated in the symptomatic treatment of dry cough.

4.2. Posology and method of administration

Method of administration:
For oral use. Administer preferably morning, noon and night.
It is advisable to administer the product before meals.

The recommended posology for SEKISAN Syrup is as follows:

Adults and children over the age of 12: 10 ml three times a day.

Children aged 6 to 12: 5 ml three times a day.

Children aged 2 to 6: 2.5 ml three times a day.

Elderly patients: It can be used in elderly patients, but caution must be used.
Shake the bottle of SEKISAN Syrup before use.

4.3. Contraindications

- Known hypersensitivity to cloperastine or to any of the excipients.
- Known hypersensitivity to antihistaminic agents.
- Patients receiving concomitant treatment with MAO inhibitors.
- It should not be used in children under 2 years of age.
- Pregnant or breast-feeding women.
- Patients with hereditary fructose intolerance, glucose or galactose malabsorption, or sucrase-isomaltase deficiency (See "Warnings about excipients").

4.4. Special warnings and precautions for use

Due to its mild anticholinergic activity, cloperastine should be administered with caution in patients with intraocular hypertension, narrow-angle glaucoma, prostatic hypertrophy, urine retention, hypertension, cardiac arrhythmia, myasthenia gravis, stenosing peptic ulcer or bowel obstruction affecting the oesophagus, intestine or bladder.

Persistent cough. Caution is recommended in patients with chronic cough such as smoker's cough, pulmonary emphysema or asthma, as it inhibits the cough reflex and could therefore alter expectoration and increase airway resistance.

Warnings about excipients

This medicine contains sucrose. Patients with a hereditary intolerance to fructose, glucose-galactose malabsorption, or sucrase-isomaltase deficiency must not take this medicine.

This medicinal product contains 0.45 g of sucrose per ml, which should be taken into account in the treatment of patients with diabetes mellitus.

This medicinal product can cause allergic reactions (possibly delayed) because it contains methyl parahydroxybenzoate and propyl parahydroxybenzoate.

4.5. Interaction with other medicinal products and other forms of interaction

As it has some antihistaminic activity, cloperastine can enhance the sedative effect of CNS depressors such as anxiolytics, antipsychotic drugs, barbiturates, hypnotics, narcotics, sedatives, tranquilizers, some analgesics and alcohol.

Also due to this activity, cloperastine, antihistaminic agents and anticholinergic drugs (anti-Parkinson's drugs, tricyclic antidepressants, MAO inhibitors, neuroleptic agents) can reciprocally increase their effects.

Expectorants and mucolytic drugs. Inhibition of the cough reflex could give rise to pulmonary obstruction in case of elevated volume or fluidity of bronchial secretions.

4.6. Pregnancy and lactation

Animal studies have not shown any evidence of damage to the foetus. In humans, its safety for use in pregnancy and lactation has not been established. Cloperastine should therefore not be used during pregnancy unless a doctor believes that the treatment's potential benefit for the mother exceeds all risks for the developing foetus or infant.

As it is unknown whether the drug is excreted in human milk, its use during lactation is not recommended.

4.7. Effects on ability to drive and use machines

Although rarely, cloperastine can cause drowsiness, so caution is recommended when driving or using dangerous machinery. If drowsiness is noted at normal doses of cloperastine, do not drive or handle dangerous machinery.

4.8. Undesirable effects

The frequency of adverse reactions is defined using the following convention: Common (≥1/100 to <1/10); Uncommon (≥1/1,000 to <1/100); Rare (≥1/10,000 to <1/1,000); Very rare (<1/10,000) and Not known (cannot be estimated from the available data).

Undesirable effects	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*
Immune system disorders				Allergic reaction	
Gastrointestinal disorders		Dry mouth			Gastric disturbances
Eye disorders					Accommodation disturbances
Nervous system disorders		Drowsiness			Sedation

*Cannot be estimated from the available data.

4.9. Overdose

No cases of overdose have been reported.

Intoxication can occur after ingesting quantities of SEKISAN that are much higher than the therapeutic doses.

Overdose could cause symptoms such as drowsiness, anticholinergic symptoms, hallucinations, excitation, ataxia, lack of motor coordination and convulsions. In case of overdose, symptomatic and maintenance treatment is recommended. Vomiting should be induced or stomach lavage should be performed with saline serum.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Other cough suppressants

ATC code: R05DB21

Cloperastine is a central action, non-opiate antitussive agent, which acts directly on the bulbar cough centre (without altering the respiratory centres or airways). It also has some antihistaminic and anti-spasmodic effects on the bronchial muscles. Unlike other antitussive agents, it does not depress the respiratory centres or induce dependence. The effect of cloperastine appears 20-30 minutes after its administration and lasts for 3-4 hours.

5.2. Pharmacokinetic properties

Cloperastine presents good oral bioavailability, as it is well absorbed in the gastrointestinal tract. Peak cloperastine concentrations are obtained after 60-90 minutes. Cloperastine is metabolised and rapidly eliminated in urine, preventing accumulation phenomena. Clinical studies conducted with cloperastine obtained an elimination half-life of 2.16 hours, a terminal distribution volume of 80 ml/kg and a high binding rate to plasma proteins.

5.3. Preclinical safety data

In the single and repeated dose toxicity studies conducted in experimental animals, cloperastine was well tolerated even at doses much higher than those recommended for use in humans. In animals receiving long-term treatment with the highest doses there was evidence of reversible kidney lesions, also found in the control groups.

At high doses (50 and 100 mg/kg), cloperastine did not induce sleep in guinea pigs. Furthermore, cloperastine did not increase the time of hypnosis caused by the administration of barbiturates.

In the Ames test, cloperastine showed no mutagenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sucrose
Carmellose sodium
Microcrystalline cellulose
Macrogol 2000 monostearate
Methyl parahydroxybenzoate (E-218)
Propyl parahydroxybenzoate (E-216)
Banana flavor
Purified water

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

5 years.

6.4. Special precautions for storage

Store below 30ºC.

6.5. Nature and contents of container

120-ml amber PVC bottles with "pilfer proof" cap. The box contains a dosing cup that is suitable for correct administration of the recommended doses.

6.6. Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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