

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

SYSTRAL[®]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

- Chlorphenoxamine hydrochloride 15 mg

Exipients:

- Stearic acid 51,6 mg
- Cetyl stearyl alcohol 51,5 mg
- Benzilic alcohol 0,0005 mg
- Perfume 0,4 mg
- Isopropyl myristate 70 mg
- Sodic Nipagin 2,06 mg
- Sodic Nipazol 0,22 mg
- Triethanolamine 24 mg
- Sorbitol solution 70% 100 mg
- Sodic Vaseline 50 mg
- Potassium Hydroxide 1,1 mg
- Purified water 630 mg

3. PHARMACEUTICAL FORM

Ointment for topical application.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For topical application of allergic and pruritic skin conditions, including insect bites, light burns, sunburns, chilblain, pruriginous and allergic dermatitis like the ones caused by jelly-fish, and eczema.

4.2. Posology and method of administration

Apply several times a day on the skin affected areas.

4.3. Contra-indications

Specific cutaneous processes (syphilis, tuberculosis), chicken-pox, post-vaccination reactions, mycosis, bacterial cutaneous infections and steroidal acne.

Systral[®] ointment must not be applied on large skin areas of breast feeding children and young children, for example in case of burns or sunburns. In such cases, a physician should be immediately consulted.

4.4. Special warnings and precautions for use

The extended application of large amounts or the application on extended areas may induce systemic reactions. This specially concerns the application on young children.

4.5. Interactions with other medicines and other forms

Not known to the present date.

4.6 Pregnancy and lactation

During pregnancy and lactation it should only be used if considered absolutely necessary by the physician.

4.6. Effects on ability to drive and use machines

None.

4.7. Undesirable effects

The extended application may induce cutaneous atrophy and teleangiectasies.

4.8. Overdose

The application of Systral[®] on large areas of skin with inflammatory alterations (such as major burns and sunburns) may cause adverse reaction symptoms, particularly in young children. These symptoms result from percutaneous absorption of large amounts of chlorphenoxamine hydrochloride. In isolated cases, restlessness, confusion and mydriasis may arise in children. In adult patients, fatigue and dry mouth were observed.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Anti histaminic effect:

On histaminic spasms of isolated intestine smooth muscles, as well as in the histaminic spasms of the guinea-pig bronchium, Systral[®] reached an antihistamine activity only known on the most active anti histaminic.

Anticollinergic effect:

The anticollinergic property that contradicts the state of the vagotonic reaction in the duration of the allergic phenomenon, was quantitatively analyzed in the isolated organ (spasms of the intestine according to Magnus) and by investigations in the whole animal.

Sedative Effect:

In animal experiments, Systral[®] showed a sedative effect that was totally compensated by caffeine and by theophylline, without alteration of the specific and fundamental effect.

Local anaesthetic effect:

Like any other antihistaminic, Systral[®] has a pronounced local anesthetic effect, that is, approximately equal to the effect of cocaine on the rabbit eyes.

Local tolerance:

Contrarily to the local irritating effect under the tissues that is proper to the several antihistaminic substances, a 1% solution of Systral[®] administered by subcutaneous, intramuscular and intravenous injections caused no inflammatory reactions on the tissues.

Persistence of the effect

The persistence of the Systral[®] effect was researched in subcutaneous administration on the histaminic asthma of the guinea-pig. The protection effect on a unique dosage maintains itself for 68 hours. Because of its persistent effect, Systral[®] is superior to the other antihistaminic substances in correspondent doses.

Pharmacotherapeutic group: XI-2
Classification: D04A A34

5.2. Pharmacokinetic properties

When directly applied, the chlorphenoxamine is not absorbed in sufficient quantity to produce a systemic effect. In all the other aspects, the pharmacokinetic and chlorphenoxamine metabolism is equivalent to the other benzidril ether antihistaminic.

6. PHARMACEUTICAL INFORMATION

6.1 List of excipients

Stearic acid, cetyl stearyl alcohol, benzil alcohol, perfume, isopropyl myristate, sodic nipagin, sodic nipazol, triethanolamine, sorbitol 70% solution, sodic vaseline, potassium hydroxide and purified water.

6.2 Incompatibilities

None.

6.3 Shelf life

Five years.

6.4 Special precautions for storage

Keep in a dry cool place.

6.5 Nature and contents of container

Aluminum tubes with interior protective lacquer.
Packages of 20 g.

6.6 Instructions for use/handling

Not applicable.

7. MARKETING AUTHORIZATION HOLDER

SIDEFARMA - Sociedade Industrial de Expansão Farmacêutica, S.A.
Rua da Guiné, n.º26
2689-514 Prior Velho

8. MARKETING AUTHORIZATION NUMBER

Packages of 20 g- Registration n.º 9061309

9. DATE OF FIRST AUTHORIZATION

June 4th, 1962.

10. DATE OF (PARTIAL) REVISION OF THE TEXT

October, 1994.