December 14, 2015

SUMMARY OF PRODUCTS

For **Lysantine, film-coated tablets**

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D.SP.NR.

2645

1.

NAME OF THE MEDICINAL PRODUCT

Lysantine

2.

QUANTITATIVE AND QUALITATIVE COMPOSITION

Orphenadrine hydrochloride 50 mg

Excipients:

Wheat starch

Lactose monohydrate

(See section 4.4).

All excipients are listed under pkt. 6.1.

3.

PHARMACEUTICAL FORM

Film-coated tablets

Appearance: Pink, circular, film-coated tablet.

4.

CLINICAL INFORMATION

4.1

Therapeutic indications

Parkinsonism.

4.2

Dosage and route of administration

50 mg (1 tablet) twice daily gradually increasing for optimal effect.

Maintenance dose: 150-250 mg (3-5 tablets.) Daily, maximum 400 mg (8 tablets) daily divided into several doses.

Discontinuation should be done gradually over 4-6 days to avoid Parkinson's crisis.

The drug should not be used in children as experience in treating children is insufficient.

4.3

Contraindications

• Hypersensitivity to orphenadrinhydrochlorid or to one or more of the excipients.

• untreated narrow angle glaucoma.

• Tardive dyskinesia.

• Urine retention.

• Porphyry.

4.4

Special warnings and precautions for use

Patients with the following diseases / disorders should be closely monitored:

• Prostate hyperplasia.

• Tachycardia.

• Hypertension.

• Heart, liver or kidney failure.

• Stenosis or obstruction of the gastrointestinal tract.

• Myasthenia gravis.

• Epilepsy.

• Low confusion threshold.
Discontinuation should be gradual (see section 4.2).
Contains wheat starch, which may contain gluten, but only in trace amounts, and is therefore considered
too safe for patients with celiac disease.
Lysantine contains lactose and should not be used in patients with hereditary problems
galactose intolerance, a special form of hereditary lactase deficiency (Lapp Lactase deficiency)
or glucose / galactose malabsorption.

4.5

Interaction with other medicinal products and other forms of interaction

Monoamine oxidase inhibitors, quinidine, tricyclic antidepressants and neuroleptics
the anticholinergic effect.
Concomitant treatment with chlorpromazine decreases the plasma concentration of chlorpromazine, probably due to enzyme induction in the liver.
Increasing the chlorpromazine dose may be necessary.
With concomitant treatment with haloperidol, an increase in haloperidols has been observed
plasma concentrations and haloperidol dose reduction may be required.

4.6

Pregnancy and breast-feeding

Pregnancy:
Lysantine can be used in pregnant women when they outweigh the expected benefits to the mother possible risks to the fetus.
The experience base of using Lysantin in pregnant women is poor.
Breast-feeding: Experience is lacking.

4.7

Effects on ability to drive and use machines

No labeling.
Lysantine can cause accommodation disorders and dizziness due to the side effects
affect the ability to drive or use machines to a negligible extent.

4.8

Side effects

1-10% of the treated patients can be expected to have side effects, these are mainly
dose-dependent. The most common side effects are dry mouth and
visual disturbances.

Heart

Common (≥1 / 100 to <1/10)
Tachycardia.

The nervous system

Common (≥1 / 100 to <1/10)
Uncommon (≥1 / 1,000 to <1 / 100)
Headache.
Dizziness and urge to sleep (preferably in
older).

Eyes

Common (≥1 / 100 to <1/10)
Conjunctival irritation, accommodation
disturbances, visual disturbances.

Gastrointestinal tract

Common (≥1 / 100 to <1/10)
Uncommon (≥1 / 1,000 to <1 / 100)
Dry mouth.

Gastrointestinal disorders such as nausea and
constipation.
Kidneys and urinary tract
Uncommon (≥1 / 1,000 to <1 / 100)
Urinary retention.
Mental disorders
Uncommon (≥1 / 1,000 to <1 / 100)
Unknown
Nervousness, confusion (preferably in
elderly), insomnia, hallucinations, euphoria.
Agitation.
Reporting of suspected adverse reactions
Once the drug is approved, reporting of suspected side effects is important. It allows
ongoing monitoring of the benefit / risk balance of the medicinal product. Doctors and healthcare professionals
is asked to report any suspected adverse reactions via:
www.meldenbivirkning.dk , or via e-mail to dkma@dkma.dk or by letter to
The Danish Medicines Agency, Axel Heides Gade 1, 2300 Copenhagen S.
4.9
Overdose
Symptoms:
Delirium possibly with motor restlessness. The pupils are often dilated. In case of restless tachycardia, by the way
normal or slightly accelerated heart rate. Risk of cardiac arrest, possibly coma and epileptiform cramps.
Treatment: Symptomatic.
4.10 Delivery
B
5.
PHARMACOLOGICAL PROPERTIES
5.0
Therapeutic classification
N 04 AB 02 - Anti-Parkinsonian drugs, anticholinergics
5.1
Pharmacodynamic properties
Antiparkinsonian agent, with anticholinergic effect.
5.2
Pharmacokinetic properties
Bioavailability approx. 70%. Plasma half-life for single dose 17 hours, after prolonged period 30-40 hours. Metabolized mainly in the liver. 50% is excreted through the kidneys.
5.3
Preclinical safety data
-
6.
PHARMACEUTICAL PARTICULARS
6.1
Excipients
Lactose monohydrate. Potato starch. Povidone (K 30). Wheat starch. Glycerol 85%.
Cellulose, microcrystalline. Talcum. Magnesium stearate. Ethylcellulose. Hypromellose.
Titanium dioxide (E171). Propylene glycol. Erythrosine (E127). Polysorbate 80.
6.2

Incompatibilities
Not applicable.
6.3
Storage time
5 years.
6.4
Special storage conditions
No special storage conditions.
6.5
Packaging type and pack sizes
Tablet container (plastic).
6.6
Rules for destruction and handling
No special precautions.
7.
MARKETING AUTHORIZATION HOLDER
Meda AS
Solvang 8
3450 Allerød
3451
8.
MARKETING AUTHORIZATION NUMBER
04455
9.
DATE OF FIRST MARKETING AUTHORIZATION
March 6, 1965
10.
DATE OF REVISION OF THE TEXT
December 14, 2015