SUMMARY OF THE PRODUCTS CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Fevarol®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol BP…….... 125 mg
Phenylephrine BP ……..…. 2.5 mg
Chlorpheniramine maleate BP …… 1 mg

3. PHARMACEUTICAL FORM

Syrup

4. CLINICAL DATA

4.1. Therapeutic indications

FEVAROL is indicated for the symptomatic treatment of fever, headache, nasal congestion, rhinitis associated with colds and flu.
FEVAROL also relieves the following cold / flu symptoms: Fever, headache, minor pain, sore throat, sneezing, congestion and runny nose.

4.2. Dosage and method of administration

- Children under one year: 2.5 ml three times a day
- Children between 1-5 years: 5 ml three times a day.
- Children over 5 years: 10 ml three times a day

Respect the medical prescription

4.3. Contra-indications

FEVAROL is contraindicated in case:

- Hypersensitivity to one of the constituents of the product.
- An history of stroke or risk factors likely to to promote the occurrence of stroke, because of the activity sympathomimetic alpha vasoconstrictor.
- Severe or poorly balanced hypertension in the treatment.
- Severe coronary insufficiency.
- Risk of glaucoma by closing the angle.
- Risk of urinary retention related to urethroprostatic disorders.
- A history of convulsions.
- Hepatocellular insufficiency due to the presence of paracetamol.
- Breastfeeding .

· Association with non-selective MAOIs due to the risk of paroxysmal hypertension and hyperthermia that can be fatal.

· Association with sympathomimetics, vasoconstrictors intended to decongest the nose, they are administered orally or nasally because of the risk of vasoconstriction and / or hypertensive relapses.

The combination of two decongestants is contraindicated, regardless of the route administration (oral and / or nasal): such an association is unnecessary and dangerous and corresponds to misuse.

4.4. Special warnings and precautions for use

In case of high or persistent fever, signs of superinfection or persistence symptoms beyond 5 days, a reassessment of the treatment should be made.

Special warnings
Due to the presence of paracetamol, to avoid a risk of overdose, check the absence of paracetamol in the composition of other drugs.

In adults and children over 50 kg, TOTAL PARACETAMOL DOSE

MUST NOT EXCEED 3 GRAMS PER DAY

Precautions for use

Treatment surveillance should be strengthened in elderly patients with:

- Greater sensitivity to orthostatic hypotension, vertigo and sedation,
- Chronic constipation (risk of paralytic ileus),
- Prostatic hypertrophy,
- Renal failure due to the risk of accumulation.

Taking alcoholic beverages or drugs containing alcohol during treatment
is not recommended (see section 4.5).

4.5. Interactions with other drugs and other forms of interactions

Linked to the presence of paracetamol

Taking paracetamol may interfere with the determination of glucose by the glucose method oxidase-peroxidase at abnormally high concentrations.
Taking paracetamol may affect the dosage of blood uric acid by the acid method phosphotungstic.

4.6. Pregnancy and breast feeding

The safety of use during pregnancy and during lactation has not been established.

4.7. Effects on ability to drive and use machines

Particular attention in the drivers of vehicles and users of machines on
the risk of drowsiness associated with the use of this medication, especially at the beginning of treatment.
This phenomenon is accentuated by the consumption of alcoholic beverages, medicines containing alcohol or sedative drugs.

4.8. Side effects

- Paracetamol has a low incidence of side effects. Rash and discomfort
gastric and intestinal disorders can occur.

· Chlorpheniramine may cause drowsiness.

· Phenylephrine can cause tremors, restlessness and or anxiety.

Reporting of suspected adverse reactions
The declaration of suspected side effects after authorization of the medicinal product is important. It allows continuous monitoring of the benefit / risk ratio of the drug.

4.9. Overdose

Paracetamol

Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain, Anomalies Glucose metabolism and metabolic acidosis can occur.
In case of severe intoxication, hepatic insufficiency may progress to encephalopathy, coma and the dead.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Heart rhythm disorders and pancreatitis have been reported.

Treatment

Regardless of the amount of paracetamol reported or suspected to have been ingested, N-Acetylcysteine must be administered immediately, within 24 hours of the moment ingestion in adults and adolescents. While in children, induce a vomiting using ipecac syrup.

A serum paracetamol assay should be performed as quickly as possible, but not less than 4 hours after ingestion.

Phenylephrine

Overdose of phenylephrine can cause hypertension, headaches, seizures,
cerebral hemorrhage, palpitations, paresthesia, or vomiting. Hypertension can be relieved by administration of an α-adrenergic blocking agent.

Chlorpheniramine

The manifestations of overdose with antihistamines may vary from the depression of the central nervous system to stimulation especially in children. Some signs like dry mouth, dilated pupils, flushing and symptoms gastrointestinal symptoms may occur.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

This medicine combines an antipyretic analgesic paracetamol, a decongestant phenylephrine and an antihistamine the chlorpheniramine maleate.

5.2. Pharmacokinetic properties

Paracetamol

Absorption

Oral paracetamol absorption is complete and rapid. Concentrations plasma levels are reached 30 to 60 minutes after ingestion.

Distribution

Paracetamol is rapidly distributed in all tissues, the concentrations are comparable in blood, saliva and plasma. Plasma protein binding is low.

Metabolism

Paracetamol is metabolized mainly in the liver, the 2 metabolic pathways major are glucuronidation and sulfoconjugation; this last path is quickly saturable at dosages higher than therapeutic doses. A minor path, catalyzed by cytochrome P 450, is the formation of a reactive intermediate (N-acetyl benzoquinone imine), which, under normal conditions of use, is rapidly detoxified by glutathione reduced and eliminated in the urine after conjugation to cysteine and mercaptopuric acid.

On the other hand, during massive intoxications, the quantity of this toxic metabolite is increased.

Elimination

The elimination is essentially urinary. 90% of the ingested dose is eliminated by the kidneys 24 hours, mainly in the form of glucuroconjugate (60 to 80%) and sulphoconjugate (20 to 30 %). Less than 5% is eliminated unchanged. The elimination half-life is approximately 2 hours.

Pathophysiological variations

· Renal insufficiency: in case of severe renal insufficiency (lower creatinine clearance at 10 ml / min), the elimination of paracetamol and its metabolites is delayed.

6. PHARMACEUTICAL DATA

6.1. List of excipients

Corn starch
Microcrystalline cellulose (powder)
Gelatin
Sodium benzoate
Purified Talc
Magnesium stearate
Colloidal anhydrous silicon
Sodium starch glycolate

6.2. The duration of the conversation

3 years.

6.3. Special precautions for storage

Store in a cool dry place, below 30ºC and protected from light.

6.4. Special precautions for disposal and handling

No special requirements.

6.5. Nature of primary packaging

Bottle of 60 ml

7. HOLDER OF THE MARKETING AUTHORIZATION

BEKRA PHARMA UK LTD
13, LAVINGTON
LONDON, UNITED KINGDOM

8. MARKETING AUTHORIZATION NUMBER (S)

[to be completed by the holder]

9. DOSIMETRY

Not applicable.

10. INSTRUCTIONS FOR THE PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

11. CONDITIONS OF PRESCRIPTION AND DELIVERY

Medicinal product not subject to medical prescription.