Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT:

Coldril capsules

2. QUALITATIVE AND QUANTITAVE COMPOSITION

Each capsule contains: Pseudoephedrine 30 mg, Paracetamol 500 mg and Chlorpheniramine Maleate 2 mg.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Dosage Form: Capsule
Appearance: Blue/Yellow capsules with white “Shelys” prints on blue cap and green “Coldril” prints on yellow body.

4.0 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Coldril is indicated in cold, flu, nasal congestion and associated fever, body ache and headache.

4.2 Posology and Method of Administration

For oral administration only

Adults and children aged 12 years and above – 2 capsules every 6 hours. Do not take more than 8 capsules per 24 hours. This product is not recommended for children under 12 years.

4.3 Contraindications

Coldril should not be given to patients who are being treated with monoamine oxidase inhibitor or within about two weeks of discontinuation of such treatment. Coldril is contraindicated in coronary thrombosis and thyrotoxicosis. It should be used with caution in patients with urinary retention and hypertension.

4.4 Special Warnings and Precautions for Use

If you are pregnant or under care of a doctor or receiving other prescribed medicines, consult your doctor before using this medicine. If symptoms persist consult a doctor. Coldril should be used with caution to patients with urinary retention and hypertension. It may cause drowsiness and dizziness in some persons and its use constitutes a danger to patients who drive vehicles or work with moving machineries. Avoid alcoholic drinks. Keep the medicine out of reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Taking Pseudoephedrine with sympathomimetic amines, including amphetamines, methamphetamines and ephedrine may be harmful because of the combined effects of the drugs on the cardiovascular system.

Additionally, consuming large amounts of caffeine can worsen the side effects of the pseudoephedrine.

4.6 Pregnancy and lactation

Pregnancy

The product should not be used during pregnancy without medical advice, and only if the benefits to the mother will outweigh the risks to the foetus. If used, the lowest effective dose and shortest duration of treatment should be considered.

Safe use of pseudoephedrine in pregnancy has not been established despite widespread use over many years. Caution should therefore be exercised by balancing the potential benefit of treatment to the mother against any possible hazards to the developing foetus.

In view of the possible association of foetal abnormalities with first trimester exposure to pseudoephedrine, this product should not be used during pregnancy without medical advice.
Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use.

There are no adequate data from the use of Chlorpheniramine maleate in pregnant women. The potential risk for humans is unknown. Use during the third trimester may result in reactions in the newborn or premature neonates. Not to be used during pregnancy unless considered essentially by a physician.

Breastfeeding
This product should not be used whilst breast feeding without medical advice and only if the benefits to the mother will outweigh the risks to the infant. If used, the lowest effective dose and shortest duration of treatment should be considered.

Pseudoephedrine is secreted into breast milk in small amounts but the effect of this on breast fed infants is unknown. The safety of pseudoephedrine during lactation has not been established and therefore the product should not be used during this period. Paracetamol is excreted in breast milk but not in a clinically significant amount.

Chlorpheniramine maleate and other antihistamine may inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician

4.7 Effects on ability to drive and use machines
May cause drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously hamper the patients' ability to drive and use machinery.

4.8 Undesirable Effects
Common undesirable effects are blurred vision, diplopia, fatigue, dizziness, sedation and dryness of the mouth, throat and nose. Occasionally abdominal pain with vomiting or diarrhoea, anxiety restlessness, nausea, muscular weakness, tremor and sweating may occur. Purpura may occur. Renal damage may occur rarely after long time usage.

4.9 Overdose
Large doses of Coldril may cause convulsions and precipitate fits in epileptics, hepatic damage may also occur. Less frequent complications include; cardiac damage, generalized bleeding, renal damage and hypoglycaemia.

Treatment
Gastric lavage should be carried out whenever the patient is seen within 4 hours. Charcoal or cholestyramine may be given but should be withheld until any necessary treatment with methionine or cysteamine has been initiated. In severe cases the treatment with methionine or cysteamine should be initiated as soon as possible within the first 10 hours to minimize damage to the liver by toxic metabolites.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamics Properties

Chlorpheniramine Maleate
Chlorpheniramine is a potent antihistamine (H1-antagonist).

Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H1-receptor sites on tissues. Chlorpheniramine also has anticholinergic activity.

Antihistamines act to prevent the release of histamine, prostaglandins and leukotrienes and have been shown to prevent the migration of inflammatory mediators. The actions of Chlorpheniramine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

Pseudoephedrine Hydrochloride
Pseudoephedrine has direct and indirect sympathomimetic activity and is an orally effective upper respiratory tract decongestant.

Pseudoephedrine is substantially less potent than ephedrine in producing both tachycardia and elevation in systolic blood pressure and considerably less potent in causing stimulation of the central nervous system.

Paracetamol
Paracetamol has analgesic and antipyretic properties but it has no useful anti-inflammatory properties. Paracetamol's effects are thought to be related to inhibition of prostaglandin synthesis.

5.2 Pharmacokinetic Properties

Chlorpheniramine Maleate
Chlorpheniramine is well absorbed from the gastro-intestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within 1 to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours. Chlorpheniramine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

Pseudoephedrine Hydrochloride
Pseudoephedrine is absorbed from the gastrointestinal tract. It is resistant to metabolism and is excreted largely unchanged in the urine. It has a half-life of several hours but elimination is enhanced and half-life shortened in acid urine.

Paracetamol
Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after oral administration. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma protein binding is negligible at usual therapeutic concentrations. Paracetamol is metabolised predominantly in the liver and excreted in the urine mainly as the glucuronide and Sulphate conjugates, with about 10% as glutathione conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1 to 4 hours.

5.3 Preclinical safety data
There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the summary of product characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Purified Talc, Maize starch, Magnesium Stearate and Empty Hard Gelatin Capsules Blue/Yellow.

6.2 Incompatibilities
None known

6.3 Shelf life

36 months

6.4 Special precautions for storage
Do not store above 30°C. Store in a dry place. Protect from Light. Keep out of reach of children.

6.5 Nature and contents of container
Coldril capsules are packed in box of 2x10 or 10x10 Aluminium foil/PVC blister packed capsules.

6.6 Special precautions for disposal and other handling
No special requirements

7.0 Name & Address of Manufacturer
Name: Shelys Pharmaceuticals Limited
Address: Plot No. 696, New Bagamoyo Road, Mwenge
Country: Tanzania
Telephone: +255 22 2771715/6/7
Telefax: +255 222772417
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AND

Name: Beta Healthcare International Limited
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8. Marketing Authorisation Number(S)
TAN 22 HM 0030

9.0 Date of first authorization/renewal of the authorization

10/01/2022

10. Date of revision of the text