SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : **Amphen Oral Suspension**
1.2 Generic Name : Chloramphenicol Palmitate Oral Suspension USP
1.3 Strength : 125 mg per 5ml
1.4 Pharmaceutical Form : Suspension

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each 5ml contains:

Chloramphenicol Palmitate	USP	
eq. to Chloramphenicol	USP	125mg
Flavoured base		q.s.

3. PHARMACEUTICAL FORM

Suspension
White coloured, flavoured, palatable suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Amphen (Chloramphenicol) is used in the treatment of typhoid and paratyphoid fevers, but it does not eliminate the typhoid carrier state. It is also used in the treatment of pyogenic meningitis, septicaemia, K. pneumoniae infection, chronic urinary tract infection with a sensitive strain of Proteus vulgaris i.e. resistant to other antibiotics and rickettsial infections that do not respond to treatment with other drugs.

4.2 Posology and method of administration

500 mg every 6 hourly. Exceptionally, the dose can be doubled for severe infections e.g. septicaemia and meningitis, providing high doses, but reduced as soon as clinically indicated. A high initial dose, with the object of obtaining rapidly a high concentration in the blood, should not be given in the treatment of typhoid fever because of the release of endotoxins from the infecting organisms. Treatment should be continued for 2 or 3 days after patient's temperature has returned to normal so as to minimise the risk of relapse. Haemophilus infection, epiglottitis and pyogenic meningitis.

Amphen capsule: Adults: 50 mg / kg body wt. daily in 4 divided doses.

Amphen suspension: Children: 50-100 mg/kg body wt daily in 4 divided doses (high doses reduced as soon as clinically indicated)

Infants: Less than 2 weeks: 25 mg/kg body wt daily in 4 divided doses.

(2 weeks - 1 year): 50 mg/kg body wt daily in 4 divided doses.

4.3 Contraindications:

Chloramphenicol is contraindicated in patients with known Hypersensitivity to the chloramphenicol

4.4 Special warnings and special precautions for use:

Avoid repeated courses and prolong treatment. Reduce dosage in patients with hepatic or renal impairment. Blood count monitoring is required before and periodically during treatment. It is contraindicated in patients with leukopenia.

4.5 Interaction with other FPPs and Other forms of Interaction

The concomitant administration of Chloramphenicol with other drugs liable to depress bone marrow function should be avoided.

4.6 Pregnancy and lactation

Amphen (Chloramphenicol) should preferably be avoided during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Transient blurring of vision may occur immediately after use and driving or using machinery should not occur until the vision is clear.

4.8 Undesirable effects

The haematological toxicity of **Amphen** (Chloramphenicol) can manifest as either reversible bone marrow depression or an idiosyncratic aplastic anaemia. Other serious effects may include renal toxicity, optic neuritis, jaundice, dryness of mouth, nausea, vomiting, diarrhoea and urticarial skin rashes. Disturbance of the normal bacterial flora of the mouth and gastro-intestinal tract reduced by **Amphen** (Chloramphenicol) may be followed by excessive growth of Candida albicans and other fungi on the mucous membrane, producing stomatitis, sore tongue, rectal or vaginal irritation and rarely pneumonia.

4.9 Overdose

Symptoms include same reactions of side effects. There is no specific antidote. Immediate treatment with emesis may be carried out to recover undigested drug.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Mechanism of action:

Amphen (Chloramphenicol) is active when administered by mouth, being rapidly absorbed from the gastrointestinal tract. Chloramphenicol is active against a large number of micro-organisms e.g. aerobic gram +ve and gram -ve bacteria, anaerobic bacteria, rickettsiae, spirochaetes and Chlamydia. It is particularly active against Haemophilus influenzae, S.pneumoniae, N.meningitidis, S.typhi and paratyphi, K. pneumoniae.

5.2 Pharmacokinetic properties

Most of a chloramphenicol dose is metabolised by the liver to inactive products, the chief metabolite being a glucuronide conjugate; only 5 to 15% of chloramphenicol is excreted unchanged in the urine. The elimination half-life is approximately 4 hours.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
1	Sucrose	BP
2	Sod. Methyl Hydroxybenzoate (Sodium Methylparaben)	BP
3	Sod. Propyl Hydroxybenzoate (Sodium Propylparaben)	BP

4	Xanthan Gum	BP
5	Saccharin Sodium	BP
6	Liquid Sorbitol (Sorbitol Solution 70%)	BP
7	Tween-80	BP
8	Sodium Citrate	BP
9	Citric Acid Monohydrate	BP
10	Essence Mango Flavour S3212	IH
11	Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Protect from light. Keep container tightly closed. Keep out of reach of children. Store at a temperature not exceeding 30˚C.

6.5 Nature and contents of container

100 ml. in an amber coloured PET bottle in an inner carton

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

07029/07811/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Jan 15, 2022

10. DATE OF REVISION OF THE TEXT

01/01/2023