PROFESSIONAL INFORMATION

SCHEDULING STATUS S4

PROPRIETARY NAME AND DOSAGE FORM
PURMYCIN CAPSULES

COMPOSITION
Each capsule contains erythromycin estolate equivalent to erythromycin 250 mg

Excipients:
Black printing ink, brilliant blue (C.I. 42090), erythrosine (C.I. 45430), gelatin, lactose monohydrate, magnesium stearate, quinoline yellow (C.I. 47005), sunset yellow (C.I. 15985), titanium dioxide (C.I. 77891)

Contains sugar: Lactose monohydrate 15,0 mg

CATEGORY AND CLASS
A 20.1.1 Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION
Pharmacodynamic properties
PURMYCIN CAPSULES is a macrolide antibiotic and inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit. It may be bactericidal or bacteriostatic depending on the organism and the concentration.

The *in vitro* antibacterial spectrum of PURMYCIN CAPSULES is as follows (care must however be exercised when extrapolating these data to the clinical situation):
PURMYCIN CAPSULES is active against the following organisms:
Mycoplasma pneumoniae, Legionella pneumophilia and *L. micdadei, Campylobacter jejuni, Streptococcus pyogenes and S. pneumoniae*, Neisseria gonorrhoeae, Bacillus anthracis*, Corynebacterium diphtheriae* (especially the carrier state), *Listeria monocytogenes, Erysipelothrix rhusiopathiae, Ureaplasma urealyticum, Chlamydia trachomatis* and *Bordetella pertussis.*

PURMYCIN CAPSULES may also have some activity against the following organisms:
Streptococcus agalactiae, streptococci of the viridans group* and anaerobic streptococci*, *Clostridium perfringens** and *Cl. tetani, Treponema pallidum, Bacteroides* species.
* = sensitivity tests must be performed.

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The following organisms are resistant to PURMYCIN CAPSULES:
Staphylococcus epidermidis, Bacteroides fragilis, the majority of aerobic gram-negative bacilli, *Mycobacterium fortuitum, M. intracellulare, Staphylococcus aureus* and *Haemophilus influenzae.*

INDICATIONS

Respiratory infections:
Atypical and typical pneumonia, Legionnaire's disease, diphtheria, pharyngitis, laryngotracheitis and otitis media.

Urinary tract infections:
Uncomplicated endocervical, rectal and epydidymal infections and nonspecific urethritis.

Gastrointestinal infections:
Early bacterial gastro-enteritis.

Skin and soft tissue infections:
Erysipelas, "malignant pustules" and erythrasma.

Miscellaneous infections:
Scarlet fever, tetanus, early syphilis (in patients allergic to penicillin), gonococcal arthritis-dermatitis syndrome, meningitis and bacteremia.

Prophylactic use (in patients hypersensitive to penicillin):
Rheumatic fever and bacterial endocarditis.

CONTRAINDICATIONS

Patients with impaired liver function or patients who have developed jaundice or other symptoms of liver toxicity during previous treatment with erythromycin.

Patients with known hypersensitivity to any of the ingredients, including excipients of PURMYCIN CAPSULES.

PURMYCIN CAPSULES may be unsafe in patients with acute porphyria as it can be porphyrinogenic.

WARNINGS AND SPECIAL PRECAUTIONS

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

KEEP OUT OF REACH OF CHILDREN.

The product should not be given to patients with impaired liver function or to patients who have developed jaundice, or other symptoms of liver toxicity during previous treatment. A second course of treatment should be given with caution.

The product should not be used in patients with a known history of allergy to erythromycin.

Excipients
Lactose warning:
PURMYCIN CAPSULES contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take PURMYCIN CAPSULES.

INTERACTIONS

Erythromycin has been reported to potentiate the effects of carbamazepine, corticosteroids and digoxin, probably by interfering with their metabolism.
In addition, high and potentially toxic concentrations of theophylline may result when erythromycin is administered concomitantly. The dose of theophylline should be reduced while the patient is receiving concomitant erythromycin therapy.

Erythromycin may enhance the effect of warfarin; dose adjustment of warfarin may be necessary.

Concurrent use of chloramphenicol and lincomycins together with erythromycin is to be avoided as antagonism occurs.

False elevation of serum glutamic oxaloacetic transaminase may appear in patients taking erythromycin.

Erythromycin might interfere with fluorimetric estimations or urinary catecholamines.

HUMAN REPRODUCTION

The safety of PURMYCIN CAPSULES for use during pregnancy and lactation has not been established (see WARNINGS AND SPECIAL PRECAUTIONS).

DOSAGE AND DIRECTIONS FOR USE

The usual oral dose for adults ranges from 1 g to 2 g (base) per day, usually given every 6 hours, depending on the nature and severity of the infection. For severe infections 2 g to 4 g (base) may be given daily. Twice-a-day dosing is not recommended when doses larger than 1 g daily are administered.

The medicine should be taken with a full glass of water (240 mL) on an empty stomach (either 1 hour before or 3 to 4 hours after meals).

Streptococcal infections

250 mg to 500 mg every 6 hours for 10 days to prevent occurrence of rheumatic fever or glomerulonephritis in the treatment of those patients with group A beta-haemolytic streptococcal infections.

For prevention of bacterial endocarditis following dental or oropharyngeal procedures, the dosing is 1 g orally 1,5 hours to 2 hours before the procedure followed by 500 mg every 6 hours for eight doses.

Primary syphilis

Doses of 2 g to 4 g per day for 10 to 15 days have been employed successfully in early syphilis.

Legionnaire's disease

A dose of 0,5 g to 1 g four times daily may be used.

SIDE EFFECTS

Gastrointestinal disturbances are fairly common.
Nausea, vomiting and diarrhoea may occur.

Super-infection following oral administration may occur due to resistant bacteria or fungi.

Pseudomembranous colitis may also occur.

Among the allergic reactions observed are fever, eosinophilia, and skin eruptions, which may occur alone or in combination.

Cholestatic hepatitis is the most striking allergic reaction. The illness starts after about 10 to 20 days of treatment and is characterised initially by nausea, vomiting and abdominal cramps, often mimicking the symptoms of acute cholecystitis. These symptoms are followed shortly by jaundice, which may be accompanied by fever, leukocytosis, eosinophilia, and elevated activities of transaminases in plasma: the cholecystogram is usually negative. Reversible deafness has occurred after high doses of erythromycin.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

See SIDE EFFECTS.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

A white granular powder encapsulated within an opaque No. 0 capsule with a cream body and red cap printed with a mortar and pestle logo and “PURMYCIN” in black ink.

PRESENTATION

20 or 100 capsules are packed in a white polypropylene container with a white linear low density polyethylene snap-on cap, together with a leaflet; or, are packed in a white high density polyethylene container with a white polypropylene cap, together with a white silica gel capsule and a leaflet.

500 capsules are packed in an amber polyvinylchloride jar with a latex lined white high density polyethylene screw-on cap, together with a silica gel sachet and a leaflet; or, are packed in a white high density polyethylene container with a white polypropylene cap, together with a white silica gel capsule and a leaflet.

20 capsules are packed into pre-printed, patient ready, low density polyethylene bags or pre-printed metallised bank bags, then vacuum packed with low density, polyethylene film. Bags

are packed together in quantities of twenty.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.
Protect from light.
Keep the container tightly closed.
Keep in original packaging until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

L/20.1.1/145

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Adcock Ingram Limited
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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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