ansimar®

"400 mg tablets" 20 tablets - "200 mg powder for oral solution" 20 sachets -
"100mg/10 ml solution for IV injection" 3 ampoules - "20 mg/ml syrup" 200 ml bottle

Doxofylline

COMPOSITION
- 400 mg tablets
Each tablet contains:
Active ingredient Doxofylline 400 mg
Excipients Colloidal anhydrous silica, colloidal hydrated silica, pregelatinized corn starch, lactose monohydrate, polyvinylpyrrolidone, microcrystalline cellulose + sodium carboxymethylcellulose, talc, magnesium stearate.

- 100 mg/10 ml solution for IV injection
Each 10 ml ampoule contains:
Active ingredient Doxofylline 100 mg
Excipients Distilled water q.s. to 10 ml.

- 200 mg powder for oral solution (paediatric use)
Each sachet contains:
Active ingredient Doxofylline 200 mg
Excipients Sucrose, ammonium glycyrrhizate, mint essence.

- 20 mg/ml syrup
100 ml syrup contain:
Active ingredient Doxofylline 2 g
Excipients Sucrose, ethyl alcohol, methyl p-hydroxybenzoate, mint essence, ammonium glycyrrhizate, purified water q.s.

NATURE AND CONTENTS OF CONTAINER
- 400 mg tablets, cardboard box containing 20 tablets
- 100 mg/10 ml ampoules, cardboard box containing 3 ampoules
- 200 mg sachet, cardboard box containing 20 sachets
- 20 mg/ml syrup, 200 ml bottle

PHARMACOTHERAPEUTIC GROUP
Xanthine derivative, antiasthmatic for systemic use.

MARKETING AUTHORISATION HOLDER
ABC FARMACEUTICI S.p.A. - ABC International Division - Corso Vittorio Emanuele II, 72 - 10121 Turin - Italy

MANUFACTURER AND END CONTROLLER
- *Tablets:*
ABC Farmaceutici S.p.A. - Canton Moretti, 29 - 10090 San Bernardo d'Ivrea (TO) - Italy
- *Ampoules:*
BIOLOGICI ITALIA LABORATORIES - Via Filippo Serpero, 2 - Masate (MI) - Italy
BIOLAB SPA - Via Buozzi, 2 – Vimodrone (MI) - Italy
(pyrogen control)
FARMA MEDITERRANIA S.L. C/Sant Sebastià, s/n - Sant Just Desvern - Barcellona (Spain)
- *Syrup:*
ABC Farmaceutici S.p.A. - Canton Moretti, 29 - 10090 San Bernardo d'Ivrea (TO) - Italy
- *Sachets:*
LA.FA.RE. S.r.l. - Via Benedetto Cozzolino, 77 - 80056 Ercolano (NA) - Italy

THERAPEUTIC INDICATIONS
- Bronchial asthma
- Pulmonary disease with spastic bronchial component.

CONTRAINDICATIONS
ANSIMAR® is contraindicated in individuals who have shown hypersensitivity to the medicinal product or to other xanthine derivatives. It is also contraindicated in patients with acute myocardial infarction, hypotension, and in lactating women.

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PRECAUTIONS FOR USE

ANSIMAR® should not be administered together with other xanthine derivates. A moderate use of beverages and foods containing caffeine is recommended. The combination of ANSIMAR® and ephedrine and other sympathomimetic requires caution.

The dose should be administered with caution in cardiac patients, in hypertensive patients, in elderly and in patients with severe hypoxemia, hyperthyroidism, chronic pulmonary heart disease, congestive heart failure, liver disease, peptic ulcer and in patients with impaired renal function. In particular, caution should be used in patients with congestive heart failure, as in these patients there is a significant slowing of drug clearance with prolonged high drug plasma levels following discontinuation of the drug.

INTERACTIONS

Several factors can reduce the hepatic clearance of xanthine derivatives causing an increase in plasma levels of the drug. Among these, age, congestive heart failure, chronic obstructive lung diseases, severe liver diseases, concomitant infections, concomitant administration of many drugs such as erythromycin, troleandomycin, lincomycin, clindamycin, allopurinol, cimetidine, anti-flu vaccine, propranolol. In these cases lower doses of the drug may be needed. Phenytoin, other anticonvulsants, and cigarette smoking may cause an increase in the clearance of xanthine derivatives with corresponding decrease plasma half-life. In these cases, higher doses of doxofylline may be needed.

In situations that may affect the clearance of xanthine derivatives, laboratory monitoring of plasma concentration of doxofylline is recommended to control therapeutic range.

SPECIAL WARNINGS

Use in pregnancy: investigations carried out on animals have shown that the active ingredient of the preparation ANSIMAR® does not interfere with pre-and postnatal development. However, since there is limited experience in humans during pregnancy, xanthines should be given to a pregnant woman only if clearly needed evaluating risks and benefits. The medicinal product does not affect concentration and does not compromise driving and using machines that require alertness.

For subjects playing sports activities: the use of medications containing ethyl alcohol may result in positive antidoping tests compared to the alcoholaemic limits established by some sports federations.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

POSOLOGY AND METHOD OF ADMINISTRATION

- 400 mg tablets: 1 tablet two/three times daily in adults.
- 100 mg/10ml Solution for IV injection: adults: 2 vials intravenously administered to patients in the supine position and slowly (15-20 minutes), preferably diluted, in the acute phase. The administration may be repeated every 12 hours, according to the prescribing physician.
- 200 mg powder for oral solution: school-aged children (6-12 years) 1-3 sachets per day (12-18 mg/kg), dissolved in abundant water.
- 20 mg/ml syrup: 1 measuring cup of 20 ml two/three times a day (a measuring cup of 20 ml corresponds to 400 mg doxofylline).

At the recommended dosage, plasma levels of doxofylline generally do not exceed 20 µg/ml, so it is not necessary to check these levels periodically.

In case of dosage increase it is necessary to control blood levels of the drug (therapeutic values around 10 µg/ml, toxicity level limits 20 µg/ml).

OVERDOSE

As there is no specific antidote, it is suggested that the management principles should be instituted according to symptomatic relief of cardiocirculatory shock.

UNDESIRABLE EFFECTS

After xanthine administration, nausea, vomiting, epigastric pain, cephalagia (headache), irritability, insomnia, tachycardia, extrasystole, tachypnoea and, occasionally, hyperglycaemia and albuminuria may occur. If an overdose is established, the patient may present with severe cardiac arrhythmias and tonic-clonic seizures; these symptoms could be the first sign of intoxication.

Adverse reactions may cause withdrawal from treatment. A lower dose re-challenge may be started only according to the advice of the physician after the disappearance of all signs and symptoms of toxicity.

If you notice other side effects not listed above, contact your doctor or pharmacist.

CAUTION: check expiration date printed on the package. Do not use the medicinal product after this date.

ABC INTERNATIONAL PHARMA

www.abcfarmaceutici.it

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