ZORGESIC® TABLETS
Paracetamol 500mg +
Orphenadrine 35mg

COMPOSITION:
Each tablet contains:

Paracetamol	500mg
Orphenadrine	35mg
Excipients	Q.S.

COMPOSITION:
Chaque comprimés contient:

Paracétamol	500mg
Orphénadrine	35mg
Excipients	Q.S.

DOSAGE:
As directed by the Physician.

POSOLOGIE:
Selon les directives du médecin.

Keep all medicines out of the reach of children.

Conservez tous les médicaments hors de la portée des enfants.

ZORGESIC® is a Registered Trademark of Zolon Healthcare Limited

127mm

Marketed by: / Commercialisé par:

zolon Healthcare Limited
(A member of the Emzor Group)
Edic Building,
9, Town Planning way,
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Nigeria.
www.zolonhealthcare.com

Manufactured by: / Fabriqué par:
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57.15mm

zolon

ZORGESIC® TABLETS
Paracetamol 500mg +
Orphenadrine 35mg

10 X 10 TABLETS

69.85mm

COMPOSITION:
Chaque comprimé pelliculé contient:

Diclofenac Sodium	75mg
Misoprostol	200mcg
Excipients	Q.S.

POSOLOGIE:
Selon les directives du médecin.

Magasin au-dessous de 30°C.
Protéger de la lumière.

Gardez tous les medicaments hors de portee des enfants.

BN:098T
MFD:08/2023
EXD:08/2026

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ZORGESIC® COMPRIMÉS
Paracetamol 500mg +
Orphenadrine 35mg

10 X 10 COMPRIMÉS

100% PANTONE 375 C
100% PANTONE 306 C
C=100%, M=60%, Y=20%, K=10%,
100% PANTONE 2736 C
R=255 G=0 B=0

1. Name of the medicinal product

Zorgesic tablet

2. Qualitative and quantitative composition

Each tablet contains 500mg of Paracetamol and 35mg Orphenadrine Citrate

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablet.

4. Clinical particulars

4.1 Therapeutic indications

- Tension headache,
- Occipital headaches associated with spasm of skeletal muscles in the region of the head and neck.
- Acute and traumatic conditions of the limbs and trunk: sprains, strains,
- Whiplash injuries,
- Acute torticollis,
- prolapsed intervertebral disc.

4.2 Posology and method of administration

Posology

2 tablets three times daily.

Method of administration

Zorgesic may be taken with or without food.

Zorgesic is for oral use only.

4.3 Contraindications

Glaucoma

Prostatic hypertrophy or obstruction at the bladder neck,

Myasthenia gravis

Esophageal spasm and pyloric or duodenal obstruction.

Hypersensitivity to paracetamol or orphenadrine citrate.

4.4 Special warnings and precautions for use

IDENTIFIED PRECAUTIONS

Orphenadrine citrate should be used with caution in patients with tachycardia, cardiac decompensation, coronary insufficiency or cardiac arrhythmias.

Paracetamol should be used with caution in patients with hepatic or renal dysfunction.

Concomitant treatment with other medicines that contain orphenadrine or paracetamol is not recommended.

Safety of continuous long-term therapy with orphenadrine has not been established. Therefore if orphenadrine is prescribed for prolonged use, periodic monitoring of blood, urine and liver function is recommended.

USE IN THE ELDERLY

The elderly should be advised to take a reduced dosage as they may be more susceptible to anticholinergic side effects at regular doses.

PAEDIATRIC USE

Zorgesic is not recommended for children under 12 years of age.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions have been reported between orphenadrine and phenothiazines and other drugs with antimuscarinic properties. Concomitant use with alcohol or other CNS depressants should be avoided. Anticoagulant dosage may require reduction if paracetamol medication is prolonged. Paracetamol absorption is increased by medicines that increase gastric emptying, e.g., metoclopramide, and decreased by medicines that decrease gastric emptying, e.g., propantheline, antidepressants with anticholinergic properties and narcotic analgesics. Paracetamol may increase chloramphenicol concentrations. The likelihood of paracetamol toxicity may be increased by the concomitant use of enzyme inducing agents such as alcohol or anticonvulsant medicines.

4.6 Fertility, pregnancy and lactation

EFFECTS ON FERTILITY

No data available

USE IN PREGNANCY

Pregnancy Category B2.

ZORGESIC is not recommended for use during pregnancy.

USE IN LACTATION

Zorgesic should not be taken during lactation as orphenadrine and paracetamol are excreted into breast milk.

4.7 Effects on ability to drive and use machines

Orphenadrine may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; ambulatory patients should therefore be cautioned accordingly.

4.8 Undesirable effects

Adverse effects are mainly due to the anti-cholinergic action of orphenadrine and are usually associated with higher doses.

ORPHENADRINE CITRATE

More common reactions: The known adverse effects include dryness of the mouth, tachycardia, palpitation, urinary hesitancy or retention, blurred vision, dilation of the pupils, increased ocular tension, weakness, nausea, headache, dizziness, constipation and drowsiness. These effects can usually be eliminated by reducing the dose.

Less common reactions: Sedation, skin rashes and other allergic reactions are very uncommon adverse effects. Infrequently an elderly patient may experience some degree of mental confusion. Very rare cases of aplastic anaemia associated with the use of orphenadrine have been reported.

PARACETAMOL

Reports of adverse reactions are rare. Although the following reactions have been reported, a causal relationship to the administration of paracetamol has been neither confirmed nor refuted; dyspepsia, nausea, allergic and haematological reactions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product.

4.9 Overdose

In the post-marketing experience, the most commonly reported adverse reactions observed when Zolyca was taken in overdose included somnolence, confusional state, agitation, and restlessness. Seizures were also reported.

In rare occasions, cases of coma have been reported.

Treatment of Zolyca overdose should include general supportive measures and may include haemodialysis if necessary (see section 4.2 Table 1).

5. Pharmacological properties

5.1 Pharmacodynamic properties

MECHANISM OF ACTION

Orphenadrine is a skeletal muscle relaxant. Paracetamol is an analgesic and antipyretic.

Orphenadrine is a skeletal muscle relaxant. Paracetamol is an analgesic and antipyretic.

5.2 Pharmacokinetic properties

NO DATA AVAILABLE

5.3 PRECLINICAL SAFETY DATA
Genotoxicity: No data available.
Carcinogenicity:No data available

6. Marketing authorisation holder

ZOLON HEALTHCARE LIMITED, NO 9/11 EDIC BULIDING TOWN PLANNING WAY, ILUPEJU

Manufacturer: EMZOR PHARMACEUTICALS IND.LTD, NO 13 RICHFIELD AVENUE,AJAO ESTATE,LAGOS