Parafon

Company Name: Janssen - Cilag

Generic Name: Chlorzoxazone & Paracetamol

Composition:

1 capsule contains: Chlorzoxazone 250 mg and Paracetamol 300 mg

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Pharmaceutical Form: Capsules

Pharmacological Actions:
Chlorzoxazone is a centrally acting muscle relaxant, which exerts its effect primarily at the level of the spinal cord and sub-cortical areas of the brain to inhibit multisynaptic reflex arcs responsible for producing and maintaining skeletal muscle spasm of varied etiology. Chlorzoxazone is an efficacious skeletal muscle relaxant with a long-lasting action. It is well tolerated, as proved by long term clinical experience.
Paracetamol has an analgesic effect on skeletal muscle pain and is non-irritant to the gastrointestinal tract.

The «feed-back» cycle of pain and muscular spasm is interrupted by PARAFON, rapid relief is afforded and mobility improved even in severely painful spasms of the skeletal musculature.

Pharmacokinetics:
Chlorzoxazone is completely absorbed after oral administration and peak serum concentrations are achieved after 1 to 2 hours. Following oral administration, its effect begins within an hour. Chlorzoxazone is rapidly metabolized in the liver via the cytochrome P450 isoenzyme CYP2E1, mainly to 6-hydroxychlorzoxazone and is excreted in urine primarily in a conjugated form as the glucuronide. Less than one percent of a dose of Chlorzoxazone is excreted unchanged in urine in 24 hours. The elimination half-life of Chlorzoxazone is about 1 hour.

Paracemtaol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral doses. Paracemtaol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Binding to plasma proteins is minimal at therapeutic concentrations. The elimination half-life of paracemtaol is about 1 to 3 hours. Paracemtaol is metabolized predominantly in the liver and excreted in urine mainly as glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol.
A minor hydroxylated metabolite (N-acetyl-p-benzoquinoneimine) is usually produed in very small amounts by cytochrome P450 isoenzymes (mainly CYP2E1and CYP3A4) in the liver and kidney. It is usually detoxified by conjugation with glutathione but may accumulate following paracemtaol overdosage and cause tissue damage.

Indications:
PARAFON is particularly effective in treating pain and spasm of the skeletal muscles arising in:
- Sprains and strains
- Myalgia
- Torticollis
- Tension headache
- Traumatic muscle damage
- Lumbago
- Spondylarthrosis
- Cervical root syndrome

Dose:
2 capsules 3 times daily after meals (unless otherwise prescribed by the physician)
This dosage is sufficient to maintain an adequate myotonolytic and analgesic effect throughout the day.

Contraindications:
Hypersensitivity to one of the components

Side effects :
Irritations of the gastrointestinal tract, somnolence, vertigo, headaches, nausea, over-excitability may sometimes occur. Allergic skin phenomena such as eruptions, petechiae and ecchymosis are also known to occur, but angioneurotic oedemas or anaphylactic reactions are extremely

rare. There is no certain evidence of drug related liver function disturbances.

Drug interactions :
The risk of paracemtaol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that indue liver microsomal enzymes. The absorption of paracemtaol may be accelerated by drugs such as metoclopramide. Excretion may be affected and plasma concentrations altered when givenwith probenecid. Colestramine reduces the absorption of paracemtaol if given within 1 hour of paracemtaol.
With drugs that cause drowsiness such as: certain antihistamines (e.g. diphenhydramine), antiseizure drugs (e.g.carbamazepine), medicine for sleep or anxiety (e.g., alprazolam, diazepam, zolpidem), other muscle relaxants, narcotic pain relievers (e.g., codeine), psychiatric medicines (e.g. chlorpromazine, risperidone, amitriptyline, trazodone).
The CNS effects of chlorzoxazone may be enhanced by concomitant use of other central nervous system depressants.

Pregnancy & Lactation :
PARAFON is not recommended during pregnancy or lactation since safety in pregnant women or nursing mothers has not been established.

Precautions & Warning :
There is no evidence proving that the use of PARAFON during pregnancy is harmless. In such cases, the physician must set advantages against risks of the treatment. Caution is advised with patients known to be hypersensitive to drugs.
Colour change of the urine, due to a phenolic metabolite of Chlorzoxazone may occur, but is of no significance. As with any medication, a routine medical check is indicated in the case of liver and renal diseases, and if the condition worsens, the drug treatment must be stopped.

Serious (including fatal) hepatocellular toxicity has been reported rarely in patients receiving chlorzoxazone. The mechanism is unknown but appears to be idiosyncratic and unpredictable. Factors predisposing patients to this rare event are not known.
Patients should be instructed to report early signs and/or symptoms of hepatotoxicity such as fever, rash anorexia nausea, vomiting fatigue, right upper quadrant pain dark urine or jaundice. chlorzoxazone should be discontinued immediately and a physician consulted if any of these signs or symptoms develop. Chlorzoxazone use should also be discontinued if a patient develops abnormal liver enzymes (e.g. AST, ALT, alkaline phosphatase, and bilirubin). The concomitant use of alcohol or other central nervous system depressants may have an additive effect.

Note:
PARAFON may impair reactivity even when used as prescribed. This should be taken into consideration when actively operating motor vehicles or using machinery and is even more significant when alcohol is consumed simultaneously.

Storage :
Store at room temperature (15-30°C).
Keep out of reach of children.

Package :
Box of 3 blisters, each containing 6 capsules.

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