Tylenol® Forte

Analgesic and antipyretic

Composition

Active substance: paracetamol 500 mg per tablet

Antioxidant : E 223

Properties/Actions

TYLENOL Forte has pronounced analgesic and antipyretic properties.

TYLENOL Forte has rapid effect, and it is well tolerated.

Indications/Uses

Temporary relief of mild to moderate aches and pains such as headache, toothache, muscular aches, menstrual pain and minor pain of arthritis.

Reduction of fever

Dosage/Administration

1 - 2 tablets every 4 to 6 hours, up to 3 - 4 times daily. Do not exceed recommended daily dose.

Contraindications:

Known hypersensitivity against paracetamol or any of the formulation excipients.

Special warnings and special precautions for use:

- Do not exceed recommended dose
- This product contains paracetamol. Do not take other paracetamol (also known as acetaminophen) containing medications at the same time.
- Consult your doctor if pain or fever persists or get worse, or if new symptoms occur, these could be signs of a serious condition
- Consult your doctor before use, if you are pregnant or breast-feeding
- Consult your doctor before using this product, if you have severe liver or kidney problem
- Chronic alcohol abusers should ask their doctor whether they should use paracetamol or other pain relievers or fever reducers
- Keep out of reach of children

Drug interaction: (with warfarin)

For most patients occasional use of paracetamol generally has little or no effect on the INR in patients on chronic warfarin therapy; however, there has been controversy regarding the possibility of paracetamol potentiating the anticoagulant effects of warfarin and other coumarin derivatives.

In general, for patients on chronic warfarin therapy, it is important to monitor prothrombin time (PT) or INR (International Normalized Ratio) closely whenever other medications are initiated, discontinued or taken regularly.

The liver toxic effects of Tylenol Forte may be increased by the use of alcohol.

Pregnancy and Lactation:

There are no adequate and well-controlled studies in pregnant or breast-feeding women. Review of the medical literature is consistent with the company's post-marketing safety data and indicate that paracetamol, when taken as directed, does not adversely affect the pregnant mother or fetus.

Maternal ingestion of paracetamol in recommended analgesic doses does not present a risk to the nursing infant. Paracetamol is excreted in breast milk in low concentrations (0.1% to 1.85% of the ingested maternal dose).

Undesirable Effects

Post marketing Data

Adverse drug reactions identified during post-marketing experience with therapeutic doses of paracetamol are included below;

- **Immune System Disorders**
  Very rare (<1/10,000, including isolated reports): Anaphylactic reaction, hypersensitivity
- **Skin and Subcutaneous Tissue Disorders**
  Very rare (<1/10,000, including isolated reports): Urticaria, pruritic rash, rash.

Over dosage and antidote:

Paracetamol in massive overdosage may cause hepatic toxicity in some patients. Therefore prompt medical attention is critical even if there are no apparent signs or symptoms.

In adults and adolescents (12 years of age), hepatic toxicity may occur following ingestion of greater than 7.5 to 10 grams over a period of 8 hours or less. Fatalities are infrequent (less than 3-4% of untreated cases) and have rarely been reported with overdoses of less than 15 grams.

Early symptoms following a potentially hepatotoxic overdose may include: anorexia, nausea, vomiting, diaphoresis, pallor and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. In adults and adolescents, any individual presenting with an unknown amount of paracetamol ingested or with a questionable or unreliable history about the time of ingestion, should have a plasma paracetamol level drawn and be treated with acetylcysteine.

The following additional procedures are recommended: promptly initiate gastric decontamination of the stomach: a plasma paracetamol assay should be obtained as early as possible, but no sooner than four hours following ingestion.

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose contact your doctor and get medical help immediately. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Storage conditions:

Do not store above 30°C

Package

TYLENOL Forte, 20 tablets of 500mg Paracetamol each

Shelf Life :

TYLENOL Forte must not be used after the date marked "EXP" on the pack.

Unless instructed otherwise, do not dispose of unused medicines by emptying them into your sink, toilet or storm drain.

Manufacturer

Cilag AG - Hochstrass 201 - 8250 Schaffhausen, Switzerland

Marketing Authorization Holder

Janssen - Cilag AG - Sihlbruggstrasse 111 - 6340 Baar, Switzerland

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This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists