

# Cold Control

Film coated tablets

## 1- Company name:

Egyptian Group for Pharmaceutical Industries (EGPI).

## 2- Trade name:

Cold Control Film coated tablets.

## 3- Generic name:

Acetaminophen 500 mg.  
Diphenhydramine HCl 12.5 mg.

## 4- Composition:

### Active Ingredients:

Acetaminophen 500 mg.  
Diphenhydramine HCl 12.5 mg.

### Inactive Ingredients:

Croscarmellose sodium, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene glycol, Titanium dioxide, Talc, FD&C Yellow # 6.

## 5- Pharmaceutical form:

Film Coated Tablets.

## 6- Pharmacological action:

• **Acetaminophen** is a pain reliever and fever reducer. Acetaminophen produces analgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat regulation center. Acetaminophen is equal to aspirin in analgesic and antipyretic effectiveness.

• **Diphenhydramine HCL** is an Antihistaminic which helps provide temporary relief of itchy, watery eyes, runny nose, sneezing, itching of the nose or throat due to hay fever or other respiratory allergies.

## 7- Pharmacokinetics:

• **Acetaminophen** is readily absorbed from gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral doses. It is distributed into most body tissues. It is metabolized predominantly in the liver. The elimination half life varies from about 1 to 3 hours. It is excreted in the urine.

• **Diphenhydramine hydrochloride** is well absorbed from gastrointestinal tract with peak plasma concentrations occurring about 1 to 4 hours after oral doses. It is widely distributed throughout in the body including the CNS. It is highly bound to plasma proteins. The elimination half life varies from about 2.4 to 9.3 hours. It is excreted in the urine.

## 8- Indications:

Runny nose, sneezing, headache, minor aches and pains, itching of the nose or throat and itchy, watery eyes due to hay fever.

## 9- Dosage & Administration:

### • Adults & Children 12 years and over:

Take 2 F.C. Tablets every 4 to 6 hours; not more than 8 F.C. Tablets in 24 hours.

### • Children below 12 years:

Do not use this adult product.

## 10- Contraindications:

- With any other product containing acetaminophen or diphenhydramine.
- Cold Control is contraindicated to patients are now taking a prescription *Monamine oxidase inhibitors (MAOI)*, or for 2 weeks after stopping the *MAOI* drug.
- Do not use below age of 12 years.

## 11- Side effects:

May cause some sedative effects as drowsiness, in-coordination. These sedative effects when they occur may diminish after a few days of treatment.

## 12- Drug Drug interactions:

*Monamine oxidase inhibitor (MAOI)*. Diphenhydramine inhibits CYP2D6 that partly responsible for the metabolism of some beta blockers including *Metoprolol* and the antidepressant *Venlafaxine*.

## 13- Pregnancy & lactation:

Not to be used for neither pregnant nor nursing mothers.

## 14- Precautions & warnings:

- Alcohol consumers. (with alcohol acetaminophen may cause liver damage).
- Ask a doctor before use if you have:
  - Glaucoma.
  - Trouble urinating due to an enlarged prostate gland.
  - A breathing problem such as emphysema or chronic bronchitis.
- Alcohol, sedatives and tranquilizers may increase drowsiness.
- Be careful when driving a motor vehicle or operating machinery.
- Taking more than the recommended dose (overdose) may cause liver damage.

## 15- Storage:

- Storage temperature should not exceed 30°C in a dry place.
- Carton box contains one or two strips. (AL/PVC) each one contains 10 film coated tablets and inner leaflet.

## 16- Instructions to patients:

- Do not use below age of 12 years.
- Stop drug if:
  - Pain gets worse or lasts more than 10 days.
  - Fever gets worse or lasts more than 3 days.
  - Redness or swelling is present.
  - New symptoms occur.
- Be careful when driving a motor vehicle or operating machinery.
- Taking more than the recommended dose (overdose) may cause liver damage.

## Manufactured by:

Egyptian Group For Pharmaceutical Industries (EGPI). Egypt.

