

CODEINE PHOSPHATE HEMIHYDRATE

Tablet

KOMPOSISI

Codeine 10 mg Tablet

Tiap tablet mengandung:
Codeine phosphate hemihydrate setara dengan Codeine 10 mg

Codeine 15 mg Tablet

Tiap tablet mengandung:
Codeine phosphate hemihydrate setara dengan Codeine 15 mg

Codeine 20 mg Tablet

Tiap tablet mengandung:
Codeine phosphate hemihydrate setara dengan Codeine 20 mg

FARMAKOLOGI

Codeine merupakan analgesik agonis opioid. Efek codeine terjadi apabila codeine berikatan secara agonis dengan reseptor opioid di berbagai tempat di susunan saraf pusat. Efek analgesik codeine tergantung afinitas codeine terhadap reseptor opioid tersebut. Codeine dapat meningkatkan ambang rasa nyeri dan mengubah reaksi yang timbul di korteks serebri pada waktu persepsi nyeri diterima dari thalamus. Codeine juga merupakan antitusif yang bekerja pada susunan saraf pusat dengan menekan pusat batuk.

INDIKASI

- ☐ Antitusif
- ☐ Analgesik

KONTRAINDIKASI

- ☐ Asma bronkial, emfisema paru-paru, trauma kepala, tekanan intrakranial yang meninggi, alkoholisme akut, setelah operasi saluran empedu.
- ☐ Anak di bawah 12 tahun
- ☐ Ibu menyusui
- ☐ Ibu hamil termasuk hamil at term
- ☐ Pasien dengan masalah pernapasan akut atau kronik, tanpa adanya alat resusitasi
- ☐ Pasien usia 12-18 tahun untuk indikasi analgesik

DOSIS DAN CARA PEMBERIAN

- ☐ Sebagai analgesik (diatas 18 tahun):
30–60 mg, tiap 4–6 jam sesuai kebutuhan.
- ☐ Sebagai antitusif (diatas 12 tahun):
10–20 mg, tiap 4–6 jam sesuai kebutuhan, maksimum 60 mg perhari.

EFEK SAMPING

- ☐ Dapat menimbulkan ketergantungan
- ☐ Mual, muntah, idiosinkrasi, pusing, sembelit.
- ☐ Depresi pernafasan terutama pada penderita asma, depresi jantung dan syok.

PERINGATAN DAN PERHATIAN

- ☐ Hati-hati penggunaan pada pasien dengan infark miokardial dan penderita asma.
- ☐ Hindari minuman beralkohol.
- ☐ Tidak boleh melebihi dosis yang dianjurkan karena dapat menyebabkan kerusakan fungsi hati.
- ☐ Hati-hati penggunaan obat ini pada penderita penyakit ginjal.
- ☐ Hati-hati pada pemberian jangka panjang.

INTERAKSI OBAT

- ☐ Hendaknya hati-hati dan dosis dikurangi, apabila digunakan bersama – sama dengan obat-obat depresan lain, anestetik, tranquilizer, sedatif, hipnotik dan alkohol.
- ☐ Tranquilizer terutama fenotiazin bekerja antagonis terhadap analgesik opiat agonis.
- ☐ Dekstroamfetamin dapat menghambat efek analgesik opiat agonis.
- ☐ Jangan diberikan bersama-sama dengan penghambat MAO dan dalam jangka waktu 14 hari setelah pemberian penghambat MAO.

KEMASAN

Codeine 10 mg Tablet

Dus berisi 10 strip @ 10 tablet / No. Reg.: GNL9712411810A2

Botol berisi 100 tablet / No. Reg.: GNL9712411810A1

Codeine 15 mg Tablet

Dus berisi 10 strip @ 10 tablet / No. Reg.: GNL9712411810B2

Botol berisi 100 tablet / No. Reg.: GNL9712411810B1

Codeine 20 mg Tablet

Dus berisi 10 strip @ 10 tablet / No. Reg.: GNL9712411810C2

Botol berisi 100 tablet / No. Reg.: GNL9712411810C1

Simpan pada suhu di bawah 30°C, terlindung dari cahaya.

HARUS DENGAN RESEP DOKTER

PT. KIMIA FARMA
JAKARTA-INDONESIA



33000534-03-071218

CODEINE PHOSPHATE HEMIHYDRATE

Tablet

COMPOSITION

Codeine 10 mg Tablet

Each tablet contains:
Codeine phosphate hemihydrate equivalent to Codeine 10 mg

Codeine 15 mg Tablet

Each tablet contains:
Codeine phosphate hemihydrate equivalent to Codeine 15 mg

Codeine 20 mg Tablet

Each tablet contains:
Codeine phosphate hemihydrate equivalent to Codeine 20 mg

ACTION

Codeine is an opioid agonist analgesics. Codeine effects occur when an agonist binds with opioid receptors in various places in the central nervous system. Analgesic effect of codeine depends on the affinity of opioid receptors is codeine. Codeine may increase the pain threshold and change the reactions arising in the cerebral cortex on pain perception on time received from the thalamus. Codeine is also an antitussive, who worked on the central nervous system by pressing the center cough.

INDICATION

- ☐ Antitussive
- ☐ Analgesic

CONTRAINDICATION

- ☐ Bronchial asthma, pulmonary emphysema, head trauma, intracranial pressure is elevated, acute alcoholism, after biliary tract surgery
- ☐ Children under 12 years
- ☐ Women during breastfeeding
- ☐ Pregnant women including pregnant at term
- ☐ Patients with acute or chronic respiratory problems, without the use of resuscitation
- ☐ Patients aged 12-18 years for analgesic indications

DOSAGE AND ADMINISTRATION

- ☐ As an analgesic (over 18 years):
30–60 mg, every 4–6 hours as needed.
- ☐ As an antitussive (over 12 years):
10–20 mg, every 4–6 hours as needed, maximum 60 mg daily.

SIDE EFFECTS

- ☐ It can lead to dependence.
- ☐ Nausea, vomiting, idiosinkration, dizziness, constipation.
- ☐ Respiratory depression especially in patients with asthma, cardiac depression and shock.

WARNING AND PRECAUTION

- ☐ Careful use in patients with myocardial infarction and patients with asthma.
- ☐ Avoid alcoholic beverages.
- ☐ May not exceed the recommended dose may cause liver damage.
- ☐ Be careful using this drug in patients with kidney disease.
- ☐ Be careful in granting long-term.

INTERACTION

- ☐ It should be carefully and the dose was reduced, when used in conjunction with other depressant drugs, anesthetic, tranquilizer, sedatives, hypnotics and alcohol.
- ☐ Tranquilizer especially phenothiazine worked antagonist of opiate agonist analgesics.
- ☐ Dextroamphetamine can inhibit the analgesic effects of opiate agonists.
- ☐ Do not be given together with MAO inhibitors and within 14 days after administration of MAO inhibitors.

PACKAGING

Codeine 10 mg Tablet

Boxes of 10 strips @ 10 tablets / Reg. No.: GNL9712411810A2

Bottle of 100 tablets / Reg. No.: GNL9712411810A1

Codeine 15 mg Tablet

Boxes of 10 strips @ 10 tablets / Reg. No.: GNL9712411810B2

Bottle of 100 tablets / Reg. No.: GNL9712411810B1

Codeine 20 mg Tablet

Boxes of 10 strips @ 10 tablets / Reg. No.: GNL9712411810C2

Bottle of 100 tablets / Reg. No.: GNL9712411810C1

Store at temperature below 30°C, protected from light.

ON MEDICAL PRESCRIPTION ONLY

PT. KIMIA FARMA
JAKARTA-INDONESIA



33000534-03-071218

catatan perubahan : Sesuai NIE Tanggal 02 Agustus 2018

- Perubahan nama semula "Codeine" menjadi "Codeine Phosphate Hemihydrate"
- Penambahan "Logo Obat Keras" pada Dus

 PT. Kimia Farma Plant Jakarta Jl. Rawagelam V No.1 Kawasan Industri Pulogadung Jakarta Timur 13930 Telp. 4609354 Fax. 4603143	Warna Hitam	Kode bahan : 33000534	Font : Nama Produk : Zapfhumnst Ult BT 7.06 mm Bentuk sediaan : Switzerland 3.97 mm Lain-lain: Helvetica 2.12 mm	Spv. Bang. Dis. & Form. B. Kemasan	
	Ukuran 103 x 238 mm	Revisi : 03		Asman Bang. Prod.	
	Jenis Kertas : HVS 60 g	Tanggal : 07-12-2018		Manager PM	