# SHINTAMET FILM COATED TABLET

Cimetidine (200mg,400mg)

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#### What SHINTAMET is used for

SHINTAMET is used for treatment of duodenal and gastric ulcer (ulcer in stomach lining), esophageal reflux disease (including heartburn and peptic esophagus inflammation) that due to acid reflux of stomach acid, dyspepsia (indigestion), and disease such as Zollinger-Ellison Syndrome (overproduction of gastric acid caused by growth in the pancreas).

#### How SHINTAMET works

SHINTAMET inhibit gastric acid secretion stimulated by food, histamine (chemical that cause allergy reaction), pentagastrin (synthetic substance which has the same action as the hormone gastrin), caffeine and insulin. This then further reduced total digestive enzyme. Gastric pH is increased to 5.0 or greater.

## Before you use SHINTAMET

## -When you must not use it

You must not take SHINTAMET if you have shown hypersensitivity to cimetidine or any component of this product.

## -Before you start to use it

Tell your doctor or pharmacist if you are allergic to any other medicines or you have any other health related problems.

Cimetidine should be used in pregnant or lactating mothers only when the anticipated benefits outweigh the potential risk.

## -Taking other medicines

Seek for your doctor or pharmacist advice if you intended to use SHINTAMET together with other medication. SHINTAMET may cause unwanted effects if used together with other medications, such as:

- theophylline (medicine to treat asthma)
- phenytoin (medicine to treat epilepsy)
- lidocaine (anesthetic)

- antiarrhythmic (medicines to treat irregular heart beat)
- -Benzodiazepins (medicine to treat depression)
- Beta blockers (medicine to reduce blood pressure) and Warfarin (anticoagulant)

However, you must inform them about all the medicines you are taking, including those without a prescription.

#### **How to use SHINTAMET**

#### -How much to use

The total daily dose should not exceed 2.4g.

Duodenal ulcers: 800mg/day in 1-2 divided doses or 200-400mg 3 times daily with 400mg at bedtime

Prevention of recurrent duodenal and gastric ulcer: 400mg/day

Benign gastric ulcer: 400mg 2 times daily or 200mg 3 times daily with 400mg at bedtime Reflux esophagitis: 400mg 2 times daily for mild to moderate condition. 400mg 4 times daily and at bedtime for severe condition Zollinger-Ellison syndrome and other gastric hypersecretory conditions: 200-400mg 3 times daily with 400mg at bedtime

Dyspepsia: 200mg 4 times daily and at bedtime.

Children 1-12 years: 20-25 mg/kg daily in divided dose.

## -When to use it

SHINTAMET should be taken with meals and during bedtime depending on conditions.

#### -How long to use it

The duration of taking SHINTAMET can range from 4 weeks to 6 months depending on conditions.

## -If you forget to use it

If you miss a dose if SHINTAMET and you are taking it regularly, take it as soon as possible. If it is approaching time for the next dose, do not double the dose to make up for the forgotten dose, unless advised by your health care provider. Do not take 2 doses at once.

# -If you use too much (overdose) Seek for medical attention

# While you are using it -Things you must do

Follow your doctor's instruction when you are taking SHINTAMET.

#### -Things you must not do

Do not stop taking this medicine or change the dosing regimen without instruction of your doctor.

Do not give SHINTAMET to anyone else, even if they have the same condition as you.

## -Things to be careful of

SHINTAMET must be used cautiously in people with gastric cancer, impaired kidney function, who are still neonates or newborns, during pregnancy and lactation and people on medication treatment or with illness that could cause falls in blood cell count.

#### **Side effects**

SHINTAMET commonly may cause diarrhea, dizziness, tiredness, and rashes.

This is not complete list of all possible side effects. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the

website <u>portal.bpfk.gov.my</u> (Consumers → Reporting)

## Storage and Disposal of SHINTAMET

## -Storage

Store below 30°C, protect from light and moisture.

#### -Disposal

SHINTAMET should be disposed when your doctor or pharmacist tells you to stop taking this tablet or it has passed the expiry date. Ask your pharmacist how to dispose medicines that are no longer required.

# **Product description**

## -What it looks like

SHINTAMET FILM COATED TABLET 200MG: An orange color film coated tablet.

SHINTAMET FILM COATED TABLET 400MG: A white elliptical film coated tablet, one side impressed with a score and the other side with a mark "C 400"

## -Ingredients

-Active ingredients Cimetidine -Inactive ingredients

Lactose Monohydrate

Magnesium Aluminium Silicate

Hydroxypropyl Cellulose

Sodium Starch Glycolate

Talc

Propylene Glycol

Magnesium Stearate

Dimethylpolysiloxane

Titanium Dioxide

Iron Oxide Red

Iron (III) Oxide Yellow

Hydroxypropyl Methylcellulose

## -MAL number

SHINTAMET FILM COATED TABLET 200MG

-MAL19986499A

SHINTAMET FILM COATED TABLET

400MG

-MAL19940372A

## Manufacturer

Y.S.P. Industries (M) Sdn. Bhd. Lot 3,5 & 7, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor Darul Ehsan, Malaysia.

## **Product Registration Holder**

Y.S.P. Industries (M) Sdn. Bhd. Lot 3,5 & 7, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor Darul Ehsan, Malaysia.

## **Date of revision**

18/02/2016

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