CONFIDENTIAL

1.3.2 Patient Information Leaflet (clean)

ZANTAC ORAL RANGE
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ZANTAC Tablets

ZANTAC 300 mg Tablets

ZANTAC Effervescent 150 Tablets

ZANTAC Effervescent 300 Tablets

ZANTAC Syrup

Ranitidine 150 mg or 300 mg

Read all of this leaflet carefully before you start taking ZANTAC.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ZANTAC has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT ZANTAC CONTAINS:

ZANTAC Tablets: Each tablet contains the active substance, ranitidine 150 mg (as the hydrochloride).

ZANTAC 300 mg: Each tablet contains the active substance, ranitidine 300 mg (as the hydrochloride).

The other ingredients include:

Tablet core: Croscarmellose sodium (300 mg tablet only), magnesium stearate and microcrystalline cellulose.

Film coat: Hydroxypropyl cellulose, hydroxypropyl methylcellulose 2910 and titanium dioxide (E171).

Sugar-free.

ZANTAC Effervescent 150: Each effervescent tablet contains the active substance, ranitidine 150 mg (as the hydrochloride).

Contains sugar (sorbitol): 1,14 mg/tablet.

These tablets contain aspartame as a sweetening agent and sodium benzoate.

ZANTAC 150 mg effervescent tablets contain 14,2 mmol (327 mg) of sodium per tablet.

ZANTAC Effervescent 300: Each effervescent tablet contains the active substance, ranitidine 300 mg (as the hydrochloride).

Contains sugar (sorbitol): 1,71 mg/tablet.

These tablets contain aspartame as a sweetening agent and sodium benzoate.

ZANTAC 300 mg effervescent tablets contain 20,7 mmol (476 mg) of sodium per tablet.

The other ingredients include grapefruit flavour IFF 18 C222, monosodium citrate anhydrous, orange flavour IFF 6, povidone K30 and sodium bicarbonate.

ZANTAC Syrup: Each 10 ml dosage contains the active substance, 150 mg ranitidine (as the hydrochloride). ZANTAC Syrup contains propylhydroxybenzoate 0,015 % *m/v*, butylhydroxybenzoate 0,0075 % *m/v* and ethanol 7,5 % *m/v* as preservatives.

Contains sugar (as sorbitol solution 5 g/10 ml) and saccharin sodium as a sweetening agent.

The other ingredients are: disodium hydrogen orthophosphate anhydrous, hydroxypropyl methylcellulose, mint flavour, potassium dihydrogen orthophosphate, purified water and sodium chloride.

WHAT ZANTAC IS USED FOR:

ZANTAC belongs to a group of medicines called H_2-receptor blockers. It works by reducing the amount of acid in your stomach.

In adults, ZANTAC is used to:

- to treat ulcers in the stomach, or the part that it empties into (the duodenum). In some cases your doctor may prescribe ZANTAC with antibiotics (medicines used to treat infection)
- prevent stomach ulcers which may be caused by medicines called non-steroidal anti-inflammatory medicines (NSAIDs), often used to treat arthritis
- treat problems caused by acid in the food pipe (oesophagus) or too much acid in the stomach. This can cause pain or discomfort sometimes known as indigestion or heartburn
- stop acid from coming up from the stomach while under anaesthetic during an operation.

BEFORE YOU TAKE ZANTAC:

Do not take ZANTAC:

- if you are allergic (hypersensitive) to ranitidine or any of the other ingredients listed for each formulation.

If you think this applies to you, don't take any of the ZANTAC formulations until you have checked with your doctor.

Take special care with ZANTAC:

Before you take ZANTAC your doctor needs to know:

- if you have stomach cancer
- if you have a rare condition called acute porphyria
- if you have kidney disease, your doctor may lower your dose
- if you are over 65 years old
- if you have lung disease
- if you have diabetes
- if you have any problems with your immune system
- if you have had stomach ulcers before and you are taking non-steroidal anti-inflammatory medicines (NSAID).

Check with your doctor if you think any of these apply to you.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice, before taking ZANTAC.

Driving and using machinery:

ZANTAC can make you dizzy and have other side effects that can make you less alert. Do not drive or use machines unless you are sure you are not affected.

Important information about some of the ingredients:

ZANTAC Effervescent tablets contain aspartame, which is a source of phenylalanine. If you have a condition called phenylketonuria, please check with your doctor that ZANTAC Effervescent tablets are suitable for you.

ZANTAC Effervescent tablets contain a small amount of sodium. If you are on a sodium restricted diet, please check with your doctor that ZANTAC Effervescent tablets are suitable for you.

ZANTAC Syrup contains ethanol (alcohol). Each 5 ml spoonful contains approximately 405 mg of alcohol. You may be at risk of side effects if you have liver disease, epilepsy, or have had an injury to your brain or any condition affecting your brain, or if you are an alcoholic. Check with your doctor or pharmacist that ZANTAC Syrup is suitable for you.

ZANTAC Syrup contains phenyl and butylhydroxybenzoate which may cause allergic reactions.

ZANTAC Syrup contains sorbitol. If you have been told that you have an intolerance to some sugars, you should not take ZANTAC Syrup.

Taking other medicines with ZANTAC:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Some medicines can affect how ZANTAC works, or make it more likely that you'll have side effects. ZANTAC can also affect how some other medicines work. These include:

- procainamide or n-acetylprocainamide (used to treat heart problems)
- warfarin (used to thin the blood)
- triazolam (used to treat insomnia)
- glipizide (used to lower blood glucose)
- medicines used to treat fungal infections

- atazanavir or delaviridine (used to treat HIV infection)
- gefitinib (used to treat lung cancer)
- non-steroidal anti-inflammatory medicines (NSAID) (used to treat pain and inflammation).

Tell your doctor or pharmacist if you are taking any of these.

HOW TO TAKE ZANTAC:

Always take ZANTAC exactly as your doctor has instructed you. If you are not sure ask your doctor or pharmacist.

ZANTAC should not be used in any person under the age of 18 years.

How much to take:

The usual adult dose is either:

- 150 mg in the morning and 150 mg in the evening, or
- 300 mg at bedtime.

Your exact dose will depend on your stomach condition. Your doctor will tell you the dose you should take.

Please tell your doctor if you have kidney problems, as your doctor may need to reduce your dose.

How to take:

Tablets: Swallow each tablet whole with some water

Effervescent Tablets: Place the tablet(s) in half a glass of water. Allow the tablet(s) to dissolve completely in the water before you drink it.

Syrup: Use the spoon provided to carefully measure the dose needed. Do not mix ZANTAC Syrup with anything (not even water) before swallowing it.

If you take more ZANTAC than you should:

If you take too much ZANTAC, contact your doctor or pharmacist for advice. If possible, show them the ZANTAC pack.

If you forget to take ZANTAC:

If you forget a dose, take it as soon as you remember it, unless it is nearly time for your next dose. Don't take a double dose.

Effects when treatment with ZANTAC is stopped:

It is important that you take the full course of ZANTAC. Don't stop too early, even if you begin to feel better. If you don't complete the full course, the treatment might not be effective and your symptoms may come back.

POSSIBLE SIDE EFFECTS:

ZANTAC can cause side effects.

Not all side effects reported for ZANTAC are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Conditions you need to look out for:

A severe allergic reaction: These are less frequent in people taking ZANTAC. Signs include:

- raised and itchy rash (hives)
- swelling, sometimes of the face or mouth, tongue and throat (angioedema)
- chest pain, shortness of breath, unexplained fever, wheezing or difficulty breathing
- feeling faint, especially when standing up
- collapse.

If any of the above occurs, STOP taking ZANTAC and tell your doctor immediately or go to the casualty department at your nearest hospital.

➔ These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZANTAC. You may need urgent medical attention, or hospitalisation.

Serious skin reactions: Signs include a skin rash, which may blister and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge). Contact a doctor immediately if you get any of these symptoms. STOP taking ZANTAC immediately.

➔ The above is a serious side effect. You may need urgent medical attention.

Other side effects that may occur include:

- feeling confused, depressed or seeing or hearing things that are really not there (hallucinations)
- headache, dizziness or uncontrolled muscle movement
- slow or irregular heartbeat
- inflammation of blood vessels (vasculitis)

- inflammation of the pancreas (pancreatitis), constipation, diarrhoea, feeling sick (nausea) and being sick (vomiting)
- inflammation of the liver (hepatitis), sometimes with yellowing of the whites of the eyes and the skin (jaundice)
- unusual hair loss or thinning (alopecia)
- joint or muscle pain
- inflammation of the kidney (interstitial nephritis)
- unable to get or maintain an erection (impotence)
- unusual secretion of breast milk or breast enlargement in men.

Side effects that may show up in your blood tests:

- low levels of white blood cells
- decrease in the number of blood platelets (cells that help blood to clot)
- decrease in the number of all types of blood cells
- changes to liver function.

If you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF ZANTAC:

ZANTAC Tablets, 300 mg Tablets, Effervescent 150 or 300 Tablets: Store in a dry place at or below 30 °C.

Store in the original package to protect from moisture

ZANTAC Syrup: Store at or below 25 °C.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF ZANTAC:

ZANTAC Tablets: Cartons of 30 and 60 tablets foil wrapped.

ZANTAC 300 mg: Cartons of 30 tablets foil wrapped.

ZANTAC Effervescent 150: Carton containing 1 or 2 tubes of 14 or 15 effervescent tablets.

ZANTAC Effervescent 300: Carton containing 1 or 2 tubes of 14 or 15 effervescent tablets each.

ZANTAC Syrup: 300 ml amber glass bottles, fitted with a polypropylene cap.

IDENTIFICATION OF ZANTAC:

ZANTAC Tablets: A white, film-coated round biconvex tablet engraved on one face with 'GXEC2' and plain on the other.

ZANTAC 300 mg: White, film-coated, capsule-shaped tablets, engraved on one side with 'GXEC3' and plain on the other.

ZANTAC Effervescent 150: White to pale yellow, round, bevelled tablets marked 'GS LHK' on one side and flat on the other.

ZANTAC Effervescent 300: White to pale yellow, round, bevelled tablets marked 'GS MJG' on one side and flat on the other.

ZANTAC Syrup: A clear, pale yellow liquid with the odour of mint.

REGISTRATION NUMBER:

ZANTAC Tablets: P/11.4.3/218

ZANTAC 300 mg: S/11.4.3/378

ZANTAC Effervescent 150: Z/11.4.3/303

ZANTAC Effervescent 300: Z/11.4.3/304

ZANTAC Syrup**:** W/11.4.3/277

NAME AND ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION:

Registration date:

ZANTAC Tablets: 07 September 1982

ZANTAC 300 mg: 11 August 1986

ZANTAC Effervescent 150: 01 September 1992

ZANTAC Effervescent 300: 26 June 1992

ZANTAC Syrup: 11 March 1991

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GDS-45

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