ARMITRAZ P1253/16

ARMITRAZ P1253/16

Professional Information for Medicines for Human Use

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE
ARMITRAZ (film-coated tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
ARMITRAZ (film-coated tablets):
Each film-coated tablet contains 1 mg anastrozole.

Contains sugar: lactose monohydrate 91,00 mg
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
White, biconvex, film-coated tablet debossed with 'A1' on one side and plain on the other side.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications
Treatment of early breast cancer in postmenopausal women.
Treatment of advanced breast cancer in postmenopausal women.
Efficacy has not been demonstrated in oestrogen receptor negative patients unless they have had a previous positive clinical response to tamoxifen.

4.2. Posology and method of administration
Posology
Adults including the elderly:
One 1 mg tablet to be taken orally once a day.

Special Population
Patients with renal impairment:
No dose change is recommended in patients with mild or moderate renal impairment.

Patients with hepatic impairment:
No dose change is recommended in patients with mild hepatic disease.

Elderly patients:
No specific dosage adjustments of **ARMITRAZ** are recommended based on patient age.

Paediatric population:
The safety and efficacy of **ARMITRAZ** in children under the age of 18 years has not been established.
Not recommended for use in children.

Method of administration
ARMITRAZ should be taken orally.

4.3. Contraindications
ARMITRAZ is contraindicated in:
- patients with hypersensitivity to anastrazole or to any of the ingredients of **ARMITRAZ**
- pre-menopausal women
- pregnant/lactating women
- patients with severe renal impairment (creatinine clearance less than 20 mL/min)
- patients with moderate or severe hepatic disease

4.4. Special warnings and precautions for use
ARMITRAZ should not be used in premenopausal women. The menopause should be defined biochemically (luteinizing-hormone [LH], follicle stimulating hormone [FSH], and/or oestradiol levels) in any patient where there is doubt about menopausal status. There are no data to support the use of **ARMITRAZ** with luteinizing hormone-releasing hormone (LHRH).
Co-administration of tamoxifen or oestrogen-containing therapies with **ARMITRAZ** should be avoided as this may diminish its pharmacological action (see section 4.5 and 5.1).

Effect on bone mineral density
As **ARMITRAZ** lowers circulating oestrogen levels, it may cause a reduction in bone mineral density with a possible consequent increased risk of fracture (see section 4.8).
Women with osteoporosis or at risk of osteoporosis, should have their bone mineral density formally assessed at the commencement of treatment and at regular intervals thereafter. Treatment or prophylaxis for osteoporosis should be initiated as appropriate and carefully monitored. The use of specific treatments, e.g. bisphosphonates, may stop further bone mineral loss caused by **ARMITRAZ** in postmenopausal women and could be considered (see section 4.8).

Hepatic impairment
ARMITRAZ has not been investigated in breast cancer patients with moderate or severe hepatic impairment. Exposure to anastrozole can be increased in subjects with hepatic impairment (see section 5.2); administration of **ARMITRAZ** in patients with moderate and severe hepatic impairment is contraindicated (see section 4.3).

Renal impairment
ARMITRAZ has not been investigated in breast cancer patients with severe renal impairment. Exposure to anastrozole is not increased in subjects with severe renal impairment (GRF < 30 mL/min, see section 5.2); in patients with severe renal impairment (creatinine clearance less than 20 mL/min (see section 4.3).

Paediatric population
ARMITRAZ is not recommended for use in children and adolescents as safety and efficacy have not been established in this group of patients (see section 5.1).
ARMITRAZ should not be used in boys with growth hormone deficiency in addition to growth hormone treatment. In the pivotal clinical trial, efficacy was not demonstrated and safety was not established (see section 5.1).
Since anastrozole reduces oestradiol levels, **ARMITRAZ** must not be used in girls with growth hormone deficiency in addition to growth hormone treatment.
Long-term safety data in children and adolescents are not available.

Hypersensitivity to lactose
ARMITRAZ contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take **ARMITRAZ**.

4.5. Interaction with other medicines and other forms of interaction
ARMITRAZ inhibits cytochromes P450 (CYPs) 1A2, 2C8/9 and 3A4 *in vitro*. Clinical studies with antipyrine and warfarin showed that anastrozole at a 1 mg dose did not significantly inhibit the metabolism of antipyrine and R– and S- warfarin indicating the co-administration of **ARMITRAZ** with other medicinal products is unlikely to result in clinically significant medicinal product interactions mediated by CYP enzymes.
The enzymes mediating metabolism of anastrozole have not been identified. Cimetidine, a weak, unspecific inhibitor of CYP enzymes, did not affect the plasma concentrations of anastrozole. The effect of potent CYP inhibitors is unknown.
A review of the clinical trial safety database did not reveal evidence of clinically significant interaction in patients treated with **ARMITRAZ** who also received other commonly prescribed medicinal products. There were no clinically significant interactions with bisphosphonates (see section 5.1).
Co-administration of tamoxifen or oestrogen-containing therapies with **ARMITRAZ** should be avoided as this may diminish its pharmacological action (see section 4.4 and 5.1).

4.6. Fertility, pregnancy and lactation
Pregnancy
ARMITRAZ is contraindicated during pregnancy (see section 4.3).
There is no data from the use of **ARMITRAZ** in pregnant women. Studies in animals have shown reproductive toxicity.

Breastfeeding
ARMITRAZ is contraindicated during pregnancy (see section 4.3).
There is no data on the use of **ARMITRAZ** during lactation.

Fertility
The effects of **ARMITRAZ** on fertility in humans have not been studied. Studies in animals have shown reproductive toxicity.

4.7. Effects on ability to drive and use machines
Asthenia and somnolence have been reported with the use of **ARMITRAZ** and caution should be observed when driving or operating machinery while such symptoms persist.

4.8. Undesirable effects
a. ***Summary of the safety profile***
The most frequently reported adverse reactions were headache, hot flushes, nausea, rash, arthralgia, joint stiffness, arthritis, and asthenia.

b. ***Tabulated list of adverse reactions***
Frequency groupings are defined according to the following convention:
Frequent = more frequent, very common and common;
Less frequent = single report or isolated reports, uncommon, rare, very rare

Table 1: Adverse reactions by System Organ Class and frequency

System Organ Class	Frequency	Adverse reactions
Metabolism and nutrition disorders	Frequent	Anorexia, Hypercholesterolaemia
	Less frequent	Hypercalcaemia (with or without an increase in parathyroid hormone)
Nervous system disorders	Frequent	Headache, Somnolence, Carpal Tunnel Syndrome* , Sensory disturbances (including paraesthesia, taste loss and taste perversion)
Vascular disorders	Frequent	Hot flushes
Gastrointestinal disorders	Frequent	Nausea, Diarrhoea, Vomiting
Hepatobiliary disorders	Frequent	Increases in alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase
	Less frequent	Increases in gamma-glutamyl transferase and bilirubin, Hepatitis
Skin and subcutaneous tissue disorders	Frequent	Rash, Hair thinning (alopecia), Allergic reactions
	Less frequent	Urticaria, Erythema multiforme, Anaphylactoid reaction, Cutaneous vasculitis (including some reports of Henoch-Schönlein purpura)** , Stevens-Johnson syndrome, Angioedema

DETACH BEFORE DISPENSING

SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET
ARMITRAZ (film-coated tablets)
(Anastrozole)
(Contains sugar: lactose monohydrate)

Read all of this leaflet carefully before you take ARMITRAZ
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist, nurse or other health care provider.
- **ARMITRAZ** 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 is in this leaflet:

1. What **ARMITRAZ** is and what it is used for
2. What you need to know before you take **ARMITRAZ**
3. How to take **ARMITRAZ**
4. Possible side effects
5. How to store **ARMITRAZ**
6. Contents of the pack and other information

1. What ARMITRAZ is and what it is used for
ARMITRAZ contains a substance called anastrozole. This belongs to a group of medicines called 'aromatase inhibitors'. **ARMITRAZ** is used to treat breast cancer in women who have gone through the menopause.

ARMITRAZ works by cutting down the amount of the hormone called oestrogen that your body makes. It does this by blocking a natural substance (an enzyme) in your body called 'aromatase'.

2. What you need to know before you take ARMITRAZ
Do not take ARMITRAZ:
- If you are hypersensitive (allergic) to anastrozole or any of the ingredients of **ARMITRAZ** (listed in section 6).
- If you are pregnant or breastfeeding
- If you are pre-menopausal (still have menstrual periods)
- If you have severe kidney disease
- If you have moderate or severe liver disease

If you are not sure, talk to your doctor or pharmacist before taking **ARMITRAZ**.

Warnings and precautions
Tell your doctor, pharmacist or healthcare professional before taking **ARMITRAZ**:
- if you still have menstrual periods and have not yet gone through the menopause.
- if you are taking a medicine that contains tamoxifen or medicines that contain oestrogen (see 'Other medicines and **ARMITRAZ**').
- if you have ever had a condition that affects the strength of your bones (osteoporosis).
- if you have problems with your liver or kidneys.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before being given this medicine.

Children and adolescents
ARMITRAZ has not been studied in children or adolescents and therefore should not be used in this patient population.

Other medicine and ARMITRAZ:
Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).
The use of **ARMITRAZ** with these medicines may cause undesirable interactions.

In particular tell your doctor if you are taking:
- Certain medicines used to treat breast cancer, e.g. medicines that contain tamoxifen. This is because these medicines may stop **ARMITRAZ** from working properly.
- Medicines that contain oestrogen, such as hormone replacement therapy (HRT).

Pregnancy, breastfeeding and fertility
Do not take **ARMITRAZ** if you are pregnant or breastfeeding.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking **ARMITRAZ**.
Stop taking **ARMITRAZ** if you become pregnant and talk to your doctor.

Driving and using machines
Some people may feel weak or sleepy while taking **ARMITRAZ**.
Do not drive or operate tools or machines if you experience such side effects.
It is not always possible to predict to what extent **ARMITRAZ** may interfere with your daily activities You should ensure that you do not engage in the above activities until you are aware of the measure to which **ARMITRAZ** affects you.

ARMITRAZ contains sugar
ARMITRAZ contains lactose monohydrate which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **ARMITRAZ**.

3. How to take ARMITRAZ
Do not share medicines prescribed for you with any other person. Always take **ARMITRAZ** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
The usual dose is one tablet of **ARMITRAZ** once a day.

Your doctor will tell you how long your treatment with **ARMITRAZ** will last. Do not stop any treatment unless your doctor tells you to do so.
If you have the impression that the effect of **ARMITRAZ** is too strong or too weak, tell your doctor or pharmacist.

If you take more ARMITRAZ than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ARMITRAZ
If you forget to take your tablet, just take the next dose as normal.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking ARMITRAZ
Do not stop taking your tablets unless your doctor tells you to.

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

If any of the following happens, stop taking **ARMITRAZ** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Swelling around the eyes or face, tongue or throat, (which may be a serious allergic reaction)
- An extremely severe skin reaction with ulcers or blisters on the skin (this is known as 'Stevens-Johnson syndrome').

These are all very serious side effects. If you have them, you may have had a serious reaction to **ARMITRAZ**. You may need urgent medical attention or hospitalisation.
Treatment with **ARMITRAZ** can cause:
- Headache
- Hot flushes
- Feeling sick (nausea)
- Skin rash
- Pain or stiffness in your joints
- Inflammation of the joints (arthritis)
- Feeling weak

Tell your doctor if you notice any of the following:
Frequent side effects:
- Loss of appetite
- Feeling sleepy
- Carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of the hand)
- Tickling, tingling or numbness of skin, loss/lack of taste
- Diarrhoea
- Being sick (vomiting)
- Changes in blood tests that show how well your liver is working
- Thinning of your hair (hair loss)
- Bone pain
- Muscle pain and weakness
- Vaginal dryness
- Bleeding from the vagina (usually in the first few weeks of treatment – if the bleeding continues, talk to your doctor)

Less frequent side effects:
- Changes liver function tests
- Raised or high levels of fatty substance known as cholesterol in your blood. This would be seen in a blood test
- Inflammation of the liver (hepatitis)
- Hives or nettle rash
- Trigger finger (a condition in which your finger or thumb stays in a bent position)
- Increased amounts of calcium in your blood. If you experience nausea, vomiting and thirst, you should tell your doctor, or pharmacist or nurse as you may need to have blood tests
- Inflammation of your skin that may include red patches or blisters
- Skin rash caused by hypersensitivity (this can be from allergic or anaphylactoid reaction)
- Inflammation of the small blood vessels causing red or purple colouring of the skin. Symptoms of joint, stomach, and kidney pain may occur; this is known as 'HenochSchönlein purpura'

Effects on your bones
ARMITRAZ lowers the amount of the hormone called oestrogen that is in your body. This may lower the mineral content of your bones. Your bones may be less strong and may be more likely to fracture. Your doctor will manage these risks according to treatment guidelines for managing bone health in women who have gone through the menopause. You should talk to your doctor about the risks and treatment options.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **ARMITRAZ**.

5. How to store ARMITRAZ

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
ARMITRAZ will be stored in the pharmacy.
Store at or below 25 °C.
Keep the container in the outer carton in order to protect from light.
Do not use after the expiry date stated on the blister and the carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What ARMITRAZ contains
The active substance is anastrozole.
Each film-coated tablet contains 1 mg anastrozole.
Contains sugar: lactose monohydrate 91,00 mg.

The other ingredients of **ARMITRAZ** are: lactose monohydrate, sodium starch glycolate, povidone K-30, magnesium stearate.
Coating material: MPMC 2910/hypromellose, titanium dioxide (CI 77891), macrogol/PEG

What ARMITRAZ looks like and contents of the pack
ARMITRAZ is a white, biconvex, film-coated tablet debossed with 'A1' on one side and plain on the other side.

ARMITRAZ is supplied in pre-printed cartons containing 30 tablets in 25 micron aluminium foil/clear 25 micron PVC film blister packs. Each carton contains 3 blisters of 10 film-coated tablets each and a leaflet.

HOLDER OF THE CERTIFICATE OF REGISTRATION
AUROGEN SA (PTY) LTD
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyerdal, Ext. 12, 1448
Johannesburg
South Africa

This leaflet was last revised in
28 February 2023

REGISTRATION NUMBER
54/21.12/0163.162

System Organ Class	Frequency	Adverse reactions
Musculoskeletal and connective tissue disorders	Frequent	Arthralgia/joint stiffness, Arthritis, Osteoporosis, Bone pain, Myalgia
	Less frequent	Trigger finger
Reproductive system and breast disorders	Frequent	Vaginal dryness, Vaginal bleeding ***
General disorders and administration site conditions	Frequent	Asthenia

*Events of Carpal Tunnel Syndrome have been reported in patients receiving **ARMITRAZ** treatment in clinical trials in greater numbers than those receiving treatment with tamoxifen. However, the majority of these events occurred in patients with identifiable risk factors for the development of the condition

**Since cutaneous vasculitis and Henoch-Schönlein purpura was not observed in ATAC (the Arimidex, Tamoxifen, Alone or in Combination) study, the frequency category for these events can be considered as 'Rare' (≥ 0,01 % and < 0,1 %) based on the worst value of the point estimate.

***Vaginal bleeding has been reported commonly, mainly in patients with advanced breast cancer during the first few weeks after changing from existing hormonal therapy to treatment with **ARMITRAZ**. If bleeding persists, further evaluation should be considered.

c. Description of selected adverse reactions

Cardiovascular events

In a study conducted in postmenapausal women with operable breast cancer treated for 5 years, ischaemic cardiovascular events were reported more frequently in patients treated with **ARMITRAZ** compared to those treated with tamoxifen, although the difference was not statistically significant. The observed difference was mainly due to more reports of angina pectoris and was associated with a sub-group of patients with pre-existing ischaemic heart disease.

Thromboembolism, fluid retention and dizziness have also been observed in clinical trials with **ARMITRAZ.**

Bone fractures

Fracture rates of 22 per 1000 patient-years and 15 per 1000 patient-years were observed for the **ARMITRAZ** and tamoxifen groups, respectively, after a median follow-up of 68 months. The observed fracture rate for **ARMITRAZ** is similar to the range reported in age-matched postmenopausal populations. The incidence of osteoporosis was 10,5 % in patients treated with **ARMITRAZ** and 7,3 % in patients treated with tamoxifen. It has not been determined whether the rates of fracture and osteoporosis seen in ATAC in patients on **ARMITRAZ** treatment reflect a protective effect of tamoxifen, a specific effect of **ARMITRAZ**, or both.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the 'fi.04 Adverse Drug Reactions Reporting Form'. Found under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9. Overdose

Symptoms

There is limited clinical experience of accidental overdose. In animal studies, anastrozole demonstrated low acute toxicity. Clinical trials have been conducted with various dosages of **ARMITRAZ**, up to 60 mg in a single dose given to healthy male volunteers and up to 10 mg daily given to postmenopausal women with advanced breast cancer; these dosages were well tolerated. A single dose of **ARMITRAZ** that results in life-threatening symptoms has not been established. Refer to possible side effects in the case of an overdose.

Treatment

There is no specific antidote to overdose and treatment must be symptomatic. In the management of an overdose, consideration should be given to the possibility that multiple substances may have been taken. Dialysis may be helpful because **ARMITRAZ** is not highly protein bound. General supportive care, including frequent monitoring of vital signs and close observation of the patient, is indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Enzyme inhibitors, ATC code: L02BG03

Mechanism of action

Anastrozole is a potent and highly selective non-steroidal aromatase inhibitor. In postmenopausal women, oestradiol is produced primarily from the conversion of androstenedione to oestrone through the aromatase enzyme complex in peripheral tissues. Oestrone is subsequently converted to oestradiol. Reducing circulating oestradiol levels has been shown to produce a beneficial effect in women with breast cancer. In postmenopausal women, anastrozole at a daily dose of 1 mg produced oestradiol suppression of greater than 80 % using a highly sensitive assay. Anastrozole does not possess any progestogenic, androgenic, or oestrogenic activity. Daily doses of anastrozole up to 10 mg do not have any effect on cortisol or aldosterone secretion, measured before or after standard adrenocorticotrophic hormone (ACTH) challenge testing. Corticoid supplements are therefore not needed.

5.2. Pharmacokinetic properties

Absorption

Absorption of anastrozole is rapid and maximum plasma concentrations typically occur after two hours of dosing (under fasted conditions). Food decreases the rate but not the extent of absorption. The change in the rate of absorption is not expected to result in a clinically significant effect on steady-state plasma concentrations during once daily dosing of anastrozole tablets. Approximately 90 to 95 % of plasma anastrozole steady-state concentrations are attained after 7 daily doses, and accumulation is 3- to 4-fold. There is no evidence of time or dose-dependency of anastrozole pharmacokinetic parameters.

Anastrozole pharmacokinetics are independent of age in postmenopausal women.

Distribution

Anastrozole is only 40 % bound to plasma proteins.

Biotransformation and Elimination

Anastrozole is eliminated slowly with a plasma elimination half-life of 40 to 50 hours. Anastrozole is extensively metabolised by postmenopausal women with less than 10 % of the dose excreted in the urine unchanged within 72 hours of dosing. Metabolism of anastrozole occurs by N-dealkylation, hydroxylation and glucuronidation. The metabolites are excreted primarily via the urine. Triazole, the major metabolite in plasma, does not inhibit aromatase.

Special Populations

Renal impairment

The apparent clearance (CL/F) of anastrozole, following oral administration, was not altered in volunteers with severe renal impairment (GFR < 30 ml/min), consistent with the fact that anastrozole is eliminated primarily by metabolism. Plasma anastrozole concentrations observed during long-term efficacy trials in patients with renal impairment were within the range of plasma anastrozole concentrations seen in patients without renal impairment. In patients with severe renal impairment, administration of anastrozole is contraindicated (see section 4.2 and 4.4).

Hepatic impairment

The apparent clearance (CL/F) of anastrozole, following oral administration, was approximately 30 % lower in volunteers with stable hepatic cirrhosis than in matched controls (Study 1033IL/0014). However, plasma anastrozole concentrations in the volunteers with hepatic cirrhosis were within the range of concentrations seen in normal subjects in other trials. Plasma anastrozole concentrations observed during long-term efficacy trials in patients with hepatic impairment were within the range of plasma anastrozole concentrations seen in patients without hepatic impairment. In patients with moderate to severe hepatic impairment, anastrozole is contraindicated.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

ARMITRAZ film-coated tablets contain the following inactive ingredients: lactose monohydrate, sodium starch glycolate, povidone K-30, magnesium stearate.

Coating material: MPMC 2910/hypromellose, titanium dioxide (CI 77891), macrogol/PEG

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store at or below 25 °C.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

6.5. Nature and contents of container

30 film-coated tablets are packed in printed 25 micron aluminium foil/clear 25 micron PVC film blister pack. Each carton contains 3 blisters of 10 film-coated tablets each. The blisters are further packed in pre-printed cartons with leaflet.

6.6. Special precautions for disposal

No special requirements.

7. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

AUROGEN SA (PTY) LTD
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa

8. REGISTRATION NUMBER

54/21.12/0163.162

9. DATE OF FIRST AUTHORISATION

28 February 2023

PI533975

✂ ▼DETACH BEFORE DISPENSING ✂

SKEDULERINGSTATUS

S4

PASIËNTINLIGTINGSBLAD
ARMITRAZ (filmbedekte tablette)
(Anastrosool)
(Bevat suiker: laktosemonohidraat)

Lees hierdie inligtingsblad noukeurig deur voordat jy ARMITRAZ neem

- Hou hierdie inligtingsblad. Dit mag nodig wees om dit later weer te lees.
- Indien jy enige verdere vrae het, vra gerus jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **ARMITRAZ** is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander persone deel nie. Dit kan skadelik wees vir hulle, al is hulle simptome dieselfde as joune.

Wat is in hierdie inligtingsblad:

1. Wat is **ARMITRAZ** en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy **ARMITRAZ** neem
3. Hoe om **ARMITRAZ** te neem
4. Moontlike newe-effekte
5. Hoe om **ARMITRAZ** te berg
6. Inhoud van die verpakking en ander inligting

1. Wat is ARMITRAZ en waarvoor word dit gebruik

ARMITRAZ bevat 'n bestanddeel genaamd anastrosool. Dit behoort aan 'n groep medisynes wat 'aromatase-onderdrukkers' genoem word. **ARMITRAZ** word gebruik om borskanker te behandel by vroue wat reeds deur menopouse gegaan het.

ARMITRAZ werk deur die hoeveelheid te verminder van die hormoon estrogeen wat deur jou liggaam vervaardig word. Dit word gedoen deur 'n natuurlike verbinding ('n ensiem) in jou liggaam, genaamd 'aromatase', te blokkeer.

2. Wat jy moet weet voordat jy ARMITRAZ neem

Moenie ARMITRAZ neem nie:

- Indien jy hipersensitief (allergies) vir anastrosool of vir enige van die bestanddele van **ARMITRAZ** is (gelys by afdeling 6).
- Indien jy swanger is of borsvoed.
- Indien jy pre-menopousaal is (jy menstrueer nog).
- Indien jy erge niersiekte het.
- Indien jy matige of erge lewersiekte het.

Indien jy onseker is, praat met jou dokter of apteker voordat jy **ARMITRAZ** neem.

Waarskuwings en voorsorgmaatreëls

Sê vir jou dokter, apteker of gesondheidsorgdeskundige voordat jy **ARMITRAZ** neem:

- indien jy steeds jou maandstondes kry en nog nie deur menopouse gegaan het nie.
- indien jy 'n medisyne wat tamoksifeen of medisynes wat estrogeen bevat, neem (sien 'Ander medisynes en **ARMITRAZ**').
- indien jy ook 'n toestand gehad het wat die sterkte van jou bene affekteer (osteoporose).
- indien jy probleme met jou lewer of niere het.

Indien jy onseker is of enige van bogenoemde op jou van toepassing is, bespreek dit met jou dokter of apteker voordat jy hierdie medisyne ontvang.

Kinders en adolessente

ARMITRAZ is nie by kinders of adolessente bestudeer nie en dit moet dus nie by hierdie pasiëntpopulasie gebruik word nie.

Ander medisyne en ARMITRAZ:

Sê altyd vir jou gesondheidsorgdeskundige indien jy enige ander medisyne neem (dit sluit komplementêre of tradisionele medisynes in). Gebruik van **ARMITRAZ** saam met hierdie medisynes kan ongewenste wisselwerking veroorsaak.

Sê veral vir jou dokter indien jy die volgende neem:

- Sekere medisynes wat gebruik word om borskanker te behandel, bv. medisynes wat tamoksifeen bevat. Dit is omdat hierdie medisynes kan keer dat **ARMITRAZ** behoorlik werk.
- Medisynes wat estrogeen bevat, soos hormoonvervangingsterapie (HVT).

Swangerskap, borsvoeding en vrugbaarheid

Moenie **ARMITRAZ** neem indien jy swanger is of jou baba borsvoed nie.

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of gesondheidsorgverskaffer voordat jy **ARMITRAZ** neem.

Hou op om **ARMITRAZ** te neem indien jy swanger raak en praat met jou dokter daaroor.

Bestuur en gebruik van masjiene

Sommige mense kan vaak of slaperig voel terwyl hulle **ARMITRAZ** neem.

Moenie 'n voertuig bestuur of gereedskap of masjiene hanteer indien jy sulke newe-effekte ervaar nie.

Dit is nie altyd moontlik om te voorspel hoe watter mate **ARMITRAZ** met jou daaglikse aktiwiteite mag inneng nie. Verseker asseblief dat jy nie bogenoemde aktiwiteite uitvoer nie, totdat jy weet tot watter mate **ARMITRAZ** jou affekteer.

ARMITRAZ bevat suiker

ARMITRAZ bevat laktosemonohidraat, wat 'n soort suiker is. Indien jou dokter jou ingelig het dat jy onverdraagsaam vir sekere suikers is, kontak jou dokter voordat jy **ARMITRAZ** neem.

3. Hoe om ARMITRAZ te neem

Moenie medisynes wat vir jou voorgeskryf is, met enigiemand anders deel nie. Neem **ARMITRAZ** altyd presies soos wat jou dokter vir jou aangedui het. Vra gerus jou dokter of apteker indien jy onseker is.

Die gebruiklike dosis is een tablet **ARMITRAZ** een keer 'n dag.

Jou dokter sal jou inlig hoe lank jou behandeling met **ARMITRAZ** gaan duur. Moenie enige behandeling staak nie, buiten as jou dokter sê jy moet.

Indien jy die indruk kry dat die uitwerking van **ARMITRAZ** te sterk of te swak is, bespreek dit met jou dokter of apteker.

Indien jy meer ARMITRAZ neem as wat jy behoort te neem

In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om ARMITRAZ te neem

Indien jy vergeet om jou tablet te neem, neem maar net jou volgende dosis soos gewoonlik.

Moenie 'n dubbele dosis neem om te vergoed vir die individuele dosisse wat oorgeslaan is nie.

Indien jy ophou om ARMITRAZ te neem

Moenie ophou om jou tablette te neem nie, behalwe as jou dokter sê jy moet.

4. Moontlike newe-effekte

ARMITRAZ kan newe-effekte hê.

Nie alle newe-effekte wat vir **ARMITRAZ** gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid sou verswak of indien jy enige ongunstige effekte ondervind terwyl jy **ARMITRAZ** neem, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige raadpleeg.

Indien enige van die volgende voorkom, hou op om **ARMITRAZ** te neem en sê onmiddellik vir jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal:

- Swelling om die oë, die gesig, tong of keel (wat moontlik 'n ernstige allergiese reaksie is).
- 'n Uitermatig hewige velreaksie met ulkuse of blase op die vel (dit is bekend as 'Stevens-Johnson-sindroom').

Hierdie is baie ernstige newe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige reaksie op **ARMITRAZ** gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Behandeling met **ARMITRAZ** kan die volgende veroorsaak:

- Hoofpyn
- Warm gloede
- Voel mislik (naarheid)
- Veluitslag
- Pyn of styfheid in jou gewrigte
- Inflammasie van die gewrigte (artritis)
- Voel swak.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- Verlies aan eetlus
- Voel slaperig
- Karpaletonnelsindroom (tinteling, pyn, koue gevoel, swakheid in dele van die hand)
- Krieweling, tinteling of gevoelloosheid van die vel, verlies van smaak/kan nie prosa nie
- Diarree
- Gooi op (braking)
- Veranderings in die uitslae van bloedtoetse wat aantoon hoe goed jou lewer werk
- Jou hare word yler (haarverlies)
- Beenpyn
- Spierpyn en -swakheid
- Vaginale droogheid
- Bloeding uit die vagina (gewoonlik in die eerste paar weke van behandeling – indien die bloeding aanhou, praat met jou dokter daaroor).

Newe-effekte wat minder dikwels voorkom:

- Veranderings in lewerfunksietoetse
- Verhoogde of hoë vlakke van 'n vetterige verbinding bekend as cholesterol in jou bloed. Dit sal met 'n bloedtoets gesien word.
- Inflammasie van die lewer (hepatitis)
- Galbulte of netelroos
- Snellervinger ('n toestand waar jou vinger of duim in 'n gebuigde posisie bly)
- Verhoogde hoeveelheid kalsium in jou bloed. Indien jy naarheid, braking en dors ondervind, moet jy dit vir jou dokter, apteker of verpleegkundige sê, want dit mag nodig wees dat jy bloedtoetse ondergaan.
- Inflammasie van jou vel, wat rooi kolle of blase kan insluit
- Veluitslag veroorsaak deur hipersensitiwiteit (dit kan weens 'n allergiese of anafilaktoïede reaksie wees)
- Inflammasie van die klein bloedvate, wat veroorsaak dat die vel rooi of pers verkleur. Simptome van gewrigs-, maag- en nierpyn kan voorkom; dit is bekend as 'Henoch-Schönlein se purpura'.

Uitwerking op jou bene

ARMITRAZ verminder die hoeveelheid van die hormoon genaamd estrogeen wat in jou liggaam is. Dit kan die mineraalinhoud van jou skeletbene verlaag. Jou bene kan dan moontlik nie so sterk wees nie en meer geneig wees om te breek. Jou dokter sal hierdie risiko's bestuur in ooreenstemming met behandelingsriglyne vir beengesondheid by vroues wat reeds deur die menopouse gegaan het. Jy behoort die risiko's en behandelingsopsies met jou dokter te bespreek.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker daaroor in.

Rapportering van newe-effekte

Indien jy newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte wat nie in hierdie inligtingsblad gelys word nie, in. Jy kan ook newe-effekte rapporteer via https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte te rapporteer, kan jy help om meer inligting rakende die veiligheid van **ARMITRAZ** te verskaf.

5. Hoe om ARMITRAZ te berg

BERG ALLE MEDISYNES BUITE BEREIK VAN KINDERS.

ARMITRAZ sal in die apteek geberg word.

Bêre by of onder 25 °C.

Hou in die buitenste karton om dit teen lig te beskerm.

Moenie gebruik na die vervaldatum wat op die stulpstrook en die karton voorkom nie.

Neem alle ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) wegdoen nie.

6. Inhoud van die verpakking en ander inligting

Wat ARMITRAZ bevat

Die aktiewe bestanddeel is anastrosool.

Elke filmbedekte tablet bevat 1 mg anastrosool.

Bevat suiker: laktosemonohidraat 91,00 mg.

Die ander bestanddele van **ARMITRAZ** is: laktosemonohidraat, natriumstyselglikolaat, povidoon K-30, magnesiumstearaat.

Deklagie: MPMC 2910/hipromellose, titaandioksied (CI 77891), makrogol/PEG.

Hoe ARMITRAZ lyk en inhoud van die verpakking

ARMITRAZ is 'n wit, bikonvekse, filmbedekte tablet met 'A1' aan die een kant ingepers en glad aan die ander kant.

ARMITRAZ word verskaf in voorafgedrukte kartonne wat elk 30 tablette in stulpstroke van 25 mikron aluminiumfoelie/helder 25 mikron PVC-film bevat. Elke karton bevat 3 stulpstroke van 10 filmbedekte tablette elk en 'n inligtingsblad.

HOUER VAN DIE REGISTRASIESERTIFIKAAT

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Hierdie inligtingsblad is laas hersien

28 Februarie 2023

REGISTRASIENOMMER

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