SCHEDULING STATUS

S4

ABITIG 250 mg tablets

Abiraterone acetate

Contains sugar (164,75 mg lactose monohydrate per tablet)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- ABITIG 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 ABITIG is and what it is used for

2. What you need to know before you take ABITIG

3. How to take ABITIG

4. Possible side effects

5. How to store ABITIG

6. Contents of the pack and other information.

1. What ABITIG is and what it is used for

ABITIG contains a medicine called abiraterone acetate. ABITIG stops your body from making testosterone; this can slow the growth of cancer tissue in your prostate and elsewhere. ABITIG in combination with other medicines is used to treat prostate cancer in adult men which is in an advanced stage and has spread to other parts of the body.

Signed:

2. What you need to know before you take ABITIG

Do not take ABITIG:

- If you are hypersensitive (allergic) to abiraterone acetate or any of the other ingredients of ABITIG (listed in section 6)
- If you are pregnant, trying to get pregnant or may potentially be pregnant, suspect that you are pregnant or if you are breastfeeding your baby
- If you have severe liver problems
- If you are a woman. ABITIG is for use in male patients only
- If you are taking rifampicin (used to treat tuberculosis (TB))
- In combination with ^{223}Ra (radium 223), which is used to treat prostate cancer

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking ABITIG.

Warnings and precautions:

Take special care with ABITIG:

- Women (or health care providers) who are pregnant or may be pregnant should not handle ABITIG without gloves.

Tell your doctor or pharmacist:

- If you have high blood pressure or heart failure, or low blood potassium (low blood potassium may increase the risk of heart rhythm problems).
- If you have had other heart or blood vessel problems, including heart rhythm problems, or are being treated with medicines for these conditions.
- If you have chest pain (angina).
- If you have an irregular or rapid heart rate.
- If you recently had a heart attack.
- If you have swelling in the feet, ankles, or legs.

Signed:

- If you have severe kidney problems.
- If you have liver problems.
- If you are undergoing a stressful event while taking ABITIG in combination with prednisone and prednisolone.
- If you have weakened bones (decreased bone density). Taking ABITIG in combination with prednisone or prednisolone could have an effect on your bones.
- If you have taken a medicine known as ketoconazole in the past for prostate cancer.
- If you have high blood sugar.
- If you are on chemotherapy.
- If you have gained weight rapidly.
- If you have yellowing of the skin or eyes, darkening of the urine, or severe nausea or vomiting whilst taking ABITIG, as these could be signs or symptoms of acute liver problems, which may be fatal.
- If you have anaemia (decrease in red blood cells). You may start feeling tired and weak, have pale skin, suffer from shortness of breath, chest pain, get frequent infections, headaches, or feel dizzy.
- If you experience reduced sex drive (libido).
- If you experience muscle weakness and/or muscle pain or are taking medicines known to cause muscle weakness.

If you receive radiotherapy, ABITIG must not be given in combination with radium (^{223}Ra) due to a possible increase in the risk of bone fracture or death.

If you plan to receive ^{223}Ra following treatment with ABITIG and prednisone/prednisolone, you must wait 5 days before starting treatment with ^{223}Ra.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking ABITIG.

Signed:

Blood monitoring

ABITIG may affect your liver, and you may not have any symptoms. When you are taking ABITIG, your doctor will check your blood periodically to look for any effects on your liver.

Children and adolescents:

ABITIG is not for use in children and adolescents. If ABITIG is accidentally ingested by a child or adolescent, go to the hospital immediately and take the package leaflet with you to show to the emergency doctor.

Other medicines and ABITIG:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor or pharmacist if you are currently using any of the following medicines:

Avoid using the following medicines, which are strong CYP3A4 inducers with ABITIG:

- phenytoin, carbamazepine (used to treat epilepsy)
- rifampicin, rifabutin, rifapentine (used to treat TB)
- phenobarbital (used to treat anxiety and certain types of seizures (fits))
- St John's wort (used to treat depression)

The following medicine causes an increased effect of the medicine when used in combination with ABITIG:

- dextromethorphan (used to treat cough from smoking or long-term breathing problems).

Your doctor may reduce the dose of the following medicines (which have a narrow therapeutic index and are metabolised by CYP2D6):

- metoprolol (used to treat high blood pressure and angina (chest pain))
- propranolol (used to treat high blood pressure, irregular heartbeats, shaking (tremors), social anxiety)
- desipramine, venlafaxine (used to treat depression)
- haloperidol, risperidone (used to treat psychosis, a severe mental disorder)

Signed:

- propafenone, flecainide (used to treat heart rhythm disorders)
- codeine, oxycodone, tramadol used to treat mild to moderate pain)

Androgen deprivation treatment may increase the risk of heart rhythm problems. Consult your doctor if you are receiving any of the following:

- quinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide (used to treat heart rhythm disorders)
- methadone (used to treat moderate pain)
- moxifloxacin (an antibiotic used to treat bacterial infections)
- antipsychotic medicines (used to treat mental health problems)

The following medicine may increase prostate specific antigen (PSA) levels and should not be used in combination with ABITIG:

- spironolactone (used to treat high blood pressure and heart failure)

ABITIG with food:

Taking ABITIG with food causes more of ABITIG to be absorbed by the body than is needed and this may cause serious side effects (see section 3, “How to take ABITIG”).

Pregnancy and breastfeeding:

ABITIG is not indicated for use in women.

ABITIG may cause harm to the unborn child if it is taken by women who are pregnant.

Women who are pregnant, breastfeeding or women who may be pregnant (including health care providers) should wear gloves if they need to touch or handle ABITIG.

If you are a woman who could become pregnant you should use effective contraception during treatment with SUNMATIN and for 6 months after the last dose. If you are a male patient and your female partner could become pregnant, you should use effective contraception during treatment with SUNMATIN and for 3 months after the last dose.

Signed:

Driving and using machines:

ABITIG may affect your ability to drive a vehicle and use machines. You should not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how ABITIG affects you.

ABITIG contains lactose and sodium:

ABITIG contains lactose (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 ABITIG.

ABITIG also contains sodium (4,6 mg sodium per tablet - 18,4 mg sodium per daily dose). To be taken into consideration by patients on a controlled sodium diet.

3. How to take ABITIG

Do not share medicines prescribed for you with any other person.

Always take ABITIG exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with ABITIG will last. Do not stop your treatment without discussing it with you doctor first.

If you have the impression that the effect of ABITIG is too strong or too weak, tell your doctor or pharmacist.

The usual dose is 4 tablets once a day.

Do not take ABITIG with food.

Take ABITIG at least one hour before or at least two hours after eating. Swallow the tablets whole with water. Do not break the tablets.

ABITIG is taken with a medicine called prednisone or prednisolone.

Take the prednisone or prednisolone exactly as your doctor has instructed you. You have to take prednisone or prednisolone every day you take ABITIG.

Signed:

If you take more ABITIG than you should:

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. Take along any tablets that are left, including the carton and this leaflet, so that the hospital staff can easily tell what you have taken.

If you forget to take ABITIG:

If you have missed your dose of ABITIG and/or prednisone or prednisolone by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take ABITIG and/or prednisone or prednisolone at the next regularly scheduled time.
Do not take a double dose to make up for the forgotten individual doses.
If you forget to take ABITIG and/or prednisone or prednisolone for more than one day, talk to your doctor without delay.

If you stop taking ABITIG:

Do not stop taking ABITIG and/or prednisone or prednisolone unless your doctor tells you to.

4. Possible side effects

ABITIG can have side effects.
Not all side effects reported for ABITIG are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ABITIG, please consult your health care provider for advice.

If any of the following happens, stop taking ABITIG and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

Signed:

- fainting

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- heart failure (shortness of breath, fatigue and weakness, swelling in your legs, ankles and feet, persistent cough or wheezing with white or pink blood-tinged phlegm), congestive heart failure (a chronic progressive condition in which fluid builds up within the heart and causes it not to pump efficiently), left ventricular diastolic dysfunction and decreased left ventricular ejection fraction (shortness of breath or feeling of exertion while at rest, chest pain or extreme tiredness)
- angina pectoris (a pain or uncomfortable feeling in your chest, often spreading to your arms or neck and sometimes to your shoulders and back)
- changes in the way your heart beats (beating faster or irregular)
- abnormal heart rhythm (a fluttering in the chest, chest pain, fast or slow heart beat, fainting or dizziness)
- severe infection called sepsis (fever and chills, nausea, vomiting, diarrhoea)
- too low levels of potassium in your blood (abnormal or slow heart rate, low blood pressure, cramps, weakness)
- Disease of the liver, failure of the liver to function (also called acute liver failure) which may cause yellowing of your skin and whites of the eyes (jaundice), nausea, vomiting and a general sense of feeling unwell
- high triglyceride levels in your blood (yellowish deposits of fat on or around your eyelids
- blood in your urine

Less frequent side effects:

Signed:

- adrenal insufficiency (pain in your muscles and joints, low blood pressure making you dizzy when standing up, cravings for salt)
- yellowing of your skin and eyes, dark urine, and tiredness which may be symptoms of liver problems
- rhabdomyolysis (rapid breakdown of muscle tissue causing unexplained muscle pain, tenderness or weakness)
- inflammation of your lungs (difficulty breathing, wheezing, dry cough)

Frequency unknown side effects:

- heart attack (pain in your chest, back, jaw and other areas of your upper body that lasts more than a few minutes or that goes away and comes back, shortness of breath)
- changes in the electrical activity of your heartbeat as measured by an electrocardiogram (ECG)
- The death of cells in the liver and where the liver is scarred and permanently damaged

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- urinary tract infection (strong and frequent urge to urinate, pain and burning sensation when urinating, cloudy, bloody or strong-smelling urine, abdominal pain, nausea and vomiting)
- high blood pressure
- diarrhoea, indigestion
- increased liver enzymes (alanine aminotransferase or aspartate aminotransferase) when your blood is tested
- bone fractures

Less frequent side effects:

- weak muscles

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

Signed:

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ABITIG.

5. How to store ABITIG

- Store at or below 30 °C.
- Protect from light.
- Keep in the original bottle until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Women of child-bearing age, pregnant women or those who may potentially be pregnant (including health care providers) must use protection (e.g. gloves) when handling ABITIG.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ABITIG contains:

The active substance in ABITIG is abiraterone acetate.

Each tablet contains 250 mg abiraterone acetate.

The other ingredients are:

Butylated hydroxyanisole

Croscarmellose sodium

Hypromellose

Lactose monohydrate

Magnesium stearate

Signed:

Microcrystalline cellulose

Sodium laurilsulfate

What ABITIG looks like and contents of the pack:

White to off-white, oval, biconvex, uncoated tablet debossed with “993” on one side and plain on the other side.

White, round, high density polyethylene bottle with a white, polypropylene cap.

Pack size: 120 tablets.

Holder of certificate of registration:

Ranbaxy Pharmaceuticals (Pty) Ltd - Roodepoort

14 Lautre Road

Stormill, Ext.1, Roodepoort

Johannesburg 1724

011 495 0100

This leaflet was last revised in:

26 November 2024

Registration number:

Abitig: 51/21.12/0508

Abarine: 51/21.12/0509.508

Signed:

SKEDULERINGSTATUS

S4

ABITIG 250 mg tablette

Abirateroonasetaat

Bevat suiker (164,75 mg laktosemonohidraat per tablet)

Lees hierdie hele inligtingstuk noukeurig deur voordat jy begin om ABITIG te neem.

- Hou hierdie inligtingstuk. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer as jy verdere vrae het.
- ABITIG is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met enige ander persoon deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

Wat is in hierdie inligtingstuk

1. Wat ABITIG is en waarvoor dit gebruik word

2. Wat jy moet weet voordat jy ABITIG neem

3. Hoe om ABITIG te neem

4. Moontlike newe-effekte

5. Hoe om ABITIG te bewaar

6. Inhoud van die verpakking en ander inligting.

1. Wat ABITIG is en waarvoor dit gebruik word

ABITIG bevat ‘n middel wat abirateroonasetaat genoem word. ABITIG verhoed dat jou liggaam testosteroon vervaardig; dit kan die groei van kankerweefsel in jou prostaat en op ander plekke vertraag. ABITIG, in kombinasie met ander medisyne, word gebruik om prostaatkanker by volwasse mans wat in die gevorderde stadium is en na ander dele van die liggaam versprei het, te behandel.

Signed:

2. Wat jy moet weet voordat jy ABITIG neem

Moenie ABITIG neem nie:

- As jy hipersensitief (allergies) is vir abirateroonasetaat of vir enige van die ander bestanddele van ABITIG (gelys in afdeling 6)
- As jy swanger is, probeer om swanger te raak, dalk swanger kan wees, vermoed jy is swanger, of as jy borsvoed, moet jy eers met jou dokter praat voordat jy hierdie medisyne gebruik.
- As jy ernstige lewerprobleme het
- As jy ‘n vrou is. ABITIG word slegs by manlike pasiënte gebruik.
- As jy rifampisien neem (gebruik om tuberkulose te behandel (TB))
- In kombinasie met ^{223}Ra (radium 223), wat gebruik word om prostaatkanker te behandel.

Moenie hierdie medisyne gebruik as enige van bogenoemde op jou van toepassing is nie. Voordat jy ABITIG neem, moet jy met jou dokter of apteker praat as jy onseker is.

Waarskuwings en voorsorgmaatreëls:

Tref spesiale voorsorg met ABITIG:

- Vroue (of gesondheidsorgverskaffers) wat swanger is of swanger mag wees, moet ABITIG nie sonder handskoene hanteer nie.

Lig jou dokter of apteker in:

- As jy hoë bloeddruk of hartversaking of lae kalium in die bloed het (lae kalium in die bloed kan die risiko van probleme met hartritme verhoog).
- As jy ander hart- of bloedvatprobleme het of gehad het, insluitend probleme met hartritme, of as jy behandel word met middels vir hierdie toestande.
- As jy borskaspyn het (angina).
- As jy ‘n onreëlmatige of vinnige hartritme het.
- As jy onlangs ‘n hartaanval gehad het.
- As jy swelling van jou voete, enkels of bene het.

Signed:

- As jy ernstige nierprobleme het.
- As jy lewerprobleme het.
- As jy ‘n stresvolle ervaring het terwyl jy ABITIG in kombinasie met prednisoon en prednisoloon neem.
- As jy ‘n verswakte beenstruktuur het (verlaagde beendigtheid). Die neem van ABITIG in kombinasie met prednisoon of prednisoloon kan ‘n effek op jou bene hê.
- As jy in die verlede ‘n middel, bekend as ketokonasool, vir prostaatkanker geneem het.
- As jy hoë bloedsuiker het.
- As jy chemoterapie ontvang.
- As jy vinnig gewig aangesit het.
- As jy vergeling van jou vel of oë, verdonkering van die urine of erge naarheid of braking ervaar terwyl jy ABITIG neem, aangesien hierdie tekens of simptome van akute lewerprobleme kan wees. Dit kan fataal wees.
- As jy anemie het (verlaging in rooibloedselle). Jy kan begin om moeg en swak te voel, ‘n bleek vel hê, ly aan kortasemigheid, borskaspyn ervaar, gereeld infeksie kry, hoofpyn hê of duiselig voel
- As jy verlaagde seksdrang (libido) ervaar.
- As jy spierswakheid en/of spierpyn ervaar of as jy medsiyne gebruik wat bekend is daarvoor om spierswakheid te veroorsaak.

As jy bestralingsterapie ontvang, moet ABITIG nie in kombinasie met radium (^{223}Ra) gegee word nie as gevolg van die moontlike toename in die risiko van beenbreuke of die dood.

As jy beplan om ^{223}Ra te ontvang ná behandeling met ABITIG en prednisoon/prednisoloon, moet jy 5 dae wag voordat daar met behandeling met ^{223}Ra begin word.

Voordat jy ABITIG neem, moet jy met jou dokter of apteker praat as jy nie seker is of enige van die bogenoemde op jou van toepassing is nie.

Signed:

Monitering van bloed

ABITIG kan jou lewer affekteer en jy mag nie enige simptome hê nie. Jou dokter sal jou bloed gereeld toets terwyl jy ABITIG neem om enige effekte op die lewer op te spoor.

Kinders en adolessente:

ABITIG is nie geskik vir gebruik by kinders en adolessente nie. As ABITIG per ongeluk deur ‘n kind of adolessent ingeneem word, gaan onmiddellik na die hospitaal en neem die voubiljet saam om die dokter by die noodgevalle-afdeling te wys.

Ander medisyne en ABITIG:

Lig jou gesondheidsorgverskaffer altyd in as jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in).

Lig jou dokter of apteker in as jy tans enige van die volgende medisyne gebruik:

Vermy die gebruik van die volgende medisyne, wat sterk CYP3A4-induseerders is, saam met ABITIG:

- fenitoïen, karbamasepien (gebruik om epilepsie te behandel)
- rifampisien, rifabutien, rifapentien (gebruik om TB te behandel)
- fenobarbitoon (gebruik om angstigheid en sekere tipes toevalle (aanvalle) te behandel)
- Johanneskruid (gebruik om depressie te behandel)

Die volgende medisyne veroorsaak ‘n verhoogde effek van die medisyne wanneer dit in kombinasie met ABITIG gebruik word:

- dekstrometorfaan (gebruik om rokershoes of langtermym asemhalingsprobleme te behandel).

Jou dokter mag die dosis van die volgende medisyne verlaag (wat ‘n nou terapeutiese indeks het en deur CYP2D6 gemetaboliseer word):

- metoprolol (gebruik om hoë bloeddruk en angina (borskaspyn) te behandel)
- propranolol (gebruik om hoë bloeddruk, onreëlmatige hartklop, skudding (bewerigheid), sosiale angstigheid te behandel)

Signed:

- desipramien, venlafaksien (gebruik om depressie te behandel)
- haloperidol, risperidoon (gebruik om psigose te behandel, ‘n ernstige geestesversteuring)
- propafenoon, flekaïnied (gebruik om hartritme-versteurings te behandel)
- kodeïen, oksikodoon, tramadol (gebruik om ligte tot matige pyn te behandel)

Androgeen-ontnemingsbehandeling kan die risiko van hartritme-probleme verhoog. Raadpleeg jou dokter as jy enige van die volgende ontvang:

- kinidien, disopiramied, amiodaroon, sotalol, dofetilied, ibutilied (gebruik om hartritme-versteurings te behandel)
- metadoon (gebruik om matige pyn te behandel)
- moksifloksasien (‘n antibiotikum wat gebruik word om bakteriële infeksie te behandel)
- antipsigotiese middels (gebruik om geestesversteurings te behandel)

Die volgende medisyne kan die prostaat-spesifieke-antigeenvlakke (PSA) levels verhoog en moet nie in kombinasie met ABITIG gebruik word nie:

- spironolaktoon (gebruik om hoë bloeddruk en hartversaking te behandel)

ABITIG saam met voedsel:

Die neem van ABITIG saam met voedsel veroorsaak dat meer ABITIG deur die ligaam geabsorbeer word as wat nodig is en dit kan ernstige newe-effekte veroorsaak (sien afdeling 3, “Hoe om ABITIG te neem”).

Swangerskap en borsvoeding:

ABITIG word nie aangedui vir gebruik by vroue nie.

ABITIG kan skade aan die ongebore baba veroorsaak as dit deur swanger vroue gebruik word.

Vroue wat swanger is, borsvoed of vroue wat swanger mag wees (insluitend gesondheidsorgverskaffers) moet handskoene dra as dit vir hulle nodig is om aan ABITIG te raak of dit te hanteer.

Signed:

As jy 'n vrou is wat swanger kan raak, moet jy 'n betroubare voorbehoedmiddel gebruik terwyl jy ABITIG gebruik en vir 6 maande ná jou laaste dosis. As jy 'n manlike pasiënt is en jou vroulike maat kan swanger raak, moet julle 'n betroubare voorbehoedmiddel gebruik terwyl jy ABITIG gebruik en vir 3 maande ná jou laaste dosis.

Bestuur en gebruik van masjinerie:

ABITIG kan jou vermoë om ‘n motor te bestuur of masjinerie te hanteer, affekteer. Jy moenie ‘n voertuig bestuur, masjinerie hanteer of enigiets anders doen wat jou aandag vereis nie totdat jy weet hoe ABITIG jou sal affekteer.

ABITIG bevat laktose en natrium:

ABITIG bevat laktose (wat ‘n soort suiker is). As jou dokter jou ingelig het dat jy ‘n onverdraagsaamheid teenoor sekere suikers het, moet jy jou dokter kontak voordat jy ABITIG neem. ABITIG bevat ook natrium (4,6 mg natrium per tablet - 18,4 mg natrium per daaglikse dosis). Dit moet in aanmerking geneem word by pasiënte wat op ‘n gekontroleerde natriumdieet is.

3. Hoe om ABITIG te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem ABITIG altyd presies soos wat jou dokter dit voorgeskryf het. Kontroleer met jou dokter of apteker as jy onseker is.

Jou dokter sal jou inlig oor hoe lank jou behandeling met ABITIG sal duur. Moenie met jou behandeling ophou sonder om dit eers met jou dokter te bespreek nie.

Lig jou dokter of apteker in as jy onder die indruk is dat die effek van ABITIG te sterk of te swak is.

Die normale dosis is 4 tablette een keer per dag.

Moenie ABITIG saam met voedsel neem nie.

Neem ABITIG ten minste een uur vóór of ten minste twee uur ná ete. Sluk die tablette heel in met water. Moenie die tablette breek nie.

Signed:

ABITIG word saam met medisyne wat prednisoon of prednisoloon genoem word, geneem.

Neem die prednisoon of prednisoloon presies soos wat jou dokter dit voorgeskryf het. Jy moet elke dag wat jy ABITIG neem, ook prednisoon of prednisoloon neem.

As jy meer ABITIG geneem het as wat jy behoort te neem:

In die geval van oordosering, raadpleeg jou dokter of apteker sonder verwyl. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Neem enige oorblywende tablette saam, insluitend die karton en hierdie inligtingsblad, sodat die hospitaalpersoneel maklik kan vasstel wat jy geneem het.

As jy vergeet het om ABITIG te neem:

As jy ‘n dosis van ABITIG en/of prednisoon of prednisoloon deur slegs ‘n paar uur oorgeslaan het, neem die oorgeslaande dosis so gou as wat jy onthou. As dit amper tyd is vir jou volgende dosis, slaan die oorgeslane dosis oor en neem ABITIG en/of prednisoon of prednisoloon op die volgende normale geskeduleerde tyd.

Moenie ‘n dubbele dosis neem om te vergoed vir die individuele dosisse wat jy vergeet het nie.

As jy vergeet het om ABITIG en/of prednisoon of prednisoloon vir meer as een dag te neem, moet jy sonder versuim met jou dokter praat.

As jy ophou om ABITIG te neem:

Moenie ophou om ABITIG en/of prednisoon of prednisoloon te neem nie, tensy jou dokter jou inlig om dit te doen.

4. Moontlike newe-effekte

ABITIG kan newe-effekte hê.

Signed:

Nie alle newe-effekte wat vir ABITIG aangemeld word, is in hierdie inligtingstuk opgeneem nie. Indien jou algemene gesondheid versleg of as jy enige ongunstige effekte ervaar terwyl jy ABITIG neem, moet jy asseblief jou gesondheidsorgverskaffer raadpleeg vir advies.

As enige van die volgende gebeur, staak die gebruik van ABITIG en lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme om te sluk of asem te haal kan veroorsaak.
- uitslag of gejeuk.
- floute.

Hierdie is almal baie ernstige newe-effekte. As jy dit het, kon jy ‘n ernstige reaksie teen ABITIG gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

Dikwelse newe-effekte:

- hartversaking (kortasemigheid, moegheid en swakheid, swelling van jou bene, enkels en voete, hardnekkige hoes of hyging met wit of pienk bloedbevlekte slym), kongestiewe hartversaking (‘n chroniese toenemende toestand waarin vloeistof binne-in die hart opbou en veroorsaak dat dit nie doeltreffend kan pomp nie), linker ventrikulêre diastoliese wanfunksie en verlaagde linker ventrikulêre uitsettingsgedeelte (kortasemigheid of gevoel van inspanning terwyl in rustoestand, borskaspyn of uitermatige moegheid)
- angina pectoris (‘n pyn of ongemaklike gevoel in jou borskas wat dikwels versprei na jou arms en nek en somtyds na jou skouers en rug)
- veranderinge in die manier wat jou hart klop (klop vinniger of onreëlmatig)
- abnormale hartritme (‘n fladdering in die borskas, borskaspyn, vinnige of stadige hartklop, floute of duiseligheid)

Signed:

- ernstige infeksie wat sepsis genoem word (koors en koue rillings, naarheid, braking, diarree)
- te lae vlakke van kalium in jou bloed (abnormale of stadige hartritme, lae bloeddruk, krampe, swakheid)
- Lewersiekte, gebrek aan lewerfunksie (ook akute lewerversaking genoem) wat vergeling van jou vel en wit van jou oë (geelsug) kan veroorsaak, naarheid, braking en ‘n algemene onwel gevoel.
- hoë trigliseriedvlakke in jou bloed (geel neerslae van vet op of rondom jou ooglede)
- bloed in jou urine

Minder dikwelse newe-effekte:

- adrenale ontoereikendheid (pyn in jou spiere of gewrigte, lae bloeddruk wat veroorsaak dat jy duiselig voel as jy opstaan, behoefte aan sout)
- vergeling van die vel en oë, donker urine en moegheid wat simptome van lewerprobleme kan wees
- rabdomiolise (vinnige afbraak van spierweefsel wat onverklaarbare spierpyn, teerheid of swakheid kan veroorsaak)
- inflammasie van jou longe (moeilike asemhaling, hyging, droë hoes)

Newe-effekte met onbekende voorkoms:

- hartaanval (pyn in jou borskas, rug, kakebeen en ander areas van jou boonste liggaamsgedeelte wat meer as ‘n paar minute kan duur of wat verdwyn en weer terugkeer, kortasemigheid)
- veranderinge in die elektiese aktiwiteit van jou hartklop soos bepaal deur ‘n elektrokardiogram (EKG)
- die afsterf van selle in die lewer en waar die lewer littekens het en permanent beskadig is

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese bystand benodig.

Lig jou dokter in as jy enige van die volgende opmerk:

Dikwelse newe-effekte:

- urinienweginfeksie (sterk of gedurige drang om te urineer, pyn en branderige sensasie wanneer jy urineer, troebel, bloederige urine of urine wat sterk ruik, abdominale pyn, naarheid en braking)

Signed:

- hoë bloeddruk
- diarree, slegte spysvertering
- verhoogde lewerensieme (alanien-aminotransferase of aspartaat-aminotransferase) wanneer jou bloed getoets word
- beenbreuke

Minder dikwelse newe-effekte:

- spierswakheid

Jy moet jou dokter of apteker inlig as jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk opgeneem is nie.

Aanmelding van newe-effekte:

As jy newe-effekte ervaar, moet jy jou dokter, apteker of verpleegkundige inlig. Jy kan ook newe-effekte by SAHPRA) aanmeld *via* die Med Safety APP (Medsafety X SAHPRA) en die eReporting platform (who-umc.org, wat aanlyn beskikbaar is op SAHPRA se webblad. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van ABITIG te verskaf.

5. Hoe om ABITIG te bewaar

- Bewaar by of onder 30 °C.
- Beskerm teen lig.
- Hou die tablette in die oorspronklike bottel tot benodig vir gebruik.
- BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
- Moenie ná die vervaldatum soos op die karton gedruk, gebruik nie.
- Vroue van kinderbarende ouderdom, swanger vroue of dié wat moontlik swanger mag wees (insluitend gesondheidsorgverskaffers) moet beskerming (bv. handskoene) gebruik wanneer hulle ABITIG hanteer.
- Bring alle ongebruikte medisyne terug na jou apteker toe.
- Moenie van ongebruikte medisyne in dreinering- of rioleringstelsels (bv. toilette) ontslae raak nie.

Signed:

6. Inhoud van die verpakking en ander inligting

Wat ABITIG bevat:

Die aktiewe bestanddeel in ABITIG is abirateroonasetaat.

Elke tablet bevat 250 mg abirateroonasetaat.

Die ander bestanddele is:

Gebutileerde hidroksi-anisool

Natriumkroskarmellose

Hipromellose

Laktosemonohidraat

Magnesiumstearaat

Mikrokristallyne sellulose

Natriumlourielsulfaat

Hoe ABITIG lyk en inhoud van die verpakking:

Wit tot naaswit, ovale, bikonvekse, onbedekte tablet ingepers met “993” op die een kant en skoon op die ander kant.

Wit, ronde, hoë-digtheid-poliëtileenbottel met ‘n wit polipropileenprop.

Pakgrootte: 120 tablette.

Houer van die registrasiesertifikaat:

Ranbaxy Pharmaceuticals (Pty) Ltd - Roodepoort

Lautreweg 14

Stormill, Uitbreiding 1, Roodepoort

Johannesburg 1724

011 495 0100

Hierdie inligtingstuk was laas hersien op:

Signed:

26 November 2024

Registrasienommer:

Abitig: 51/21.12/0508

Signed: