2 Friday June 9:00 Breakfast with the neighbors

# Getting started with XTANDI

XTANDI (enzalutamide) capsules is a prescription medicine used to treat men with castration-resistant prostate cancer (prostate cancer that is resistant to medical or surgical treatments that lower testosterone) that has spread to other parts of the body and who have received treatment with docetaxel.

Please see Important Safety Information on pages 12-13 and accompanying full Prescribing Information. Continuing to fight my prostate cancer with **XTANDI** capsules. Continuing to do what matters to me.

XTANDI may cause side effects, including seizure. Please see pages 12-13 for more information.





## Learn more about XTANDI (enzalutamide) capsules

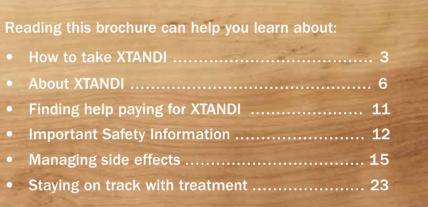
during treatment.

your treatment, too.

Throughout your treatment, be sure to work closely with your healthcare team. Together, you can find ways for you to stay on track and get the most from your treatment with XTANDI.

Please see Important Safety Information on pages 12-13 and accompanying full Prescribing Information.

Your doctor has prescribed XTANDI (ex TAN dee)—a medicine you take by mouth to help fight your prostate cancer. It's important for you to understand what to expect



You may want to share this brochure with those close to you so they can understand



## **Before starting treatment with XTANDI**

Your doctor has prescribed XTANDI (enzalutamide) capsules to help fight your prostate cancer. Before taking XTANDI, tell your doctor if you:

- Have a history of seizures, brain injury, stroke, or brain tumors
- Have any other medical conditions
- Have a partner who is pregnant or plans to become pregnant

Men who are sexually active with a pregnant woman must use a condom during and for 3 months after treatment with XTANDI. If their sexual partner may become pregnant, a condom and another form of birth control must be used during and for 3 months after treatment. Talk with your healthcare provider if you have questions about birth control.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. XTANDI can interact with many other medicines. You should not start or stop any medicine before you talk with the healthcare provider that prescribed XTANDI. Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist when you get a new medicine.

## **Taking XTANDI capsules**

It is important to take XTANDI capsules exactly as your healthcare provider tells you.

- Take your prescribed dose of XTANDI once a day
- The recommended does of XTANDI is 160 mg (four 40 mg capsules) a day
- Your healthcare provider may change your dose if needed
- Do not stop taking your prescribed dose of XTANDI without talking with your healthcare provider first
- XTANDI capsules can be taken with or without food

- room right away
- such as prednisone

Always talk with your doctor if you have any questions or concerns about your treatment with XTANDI.

Please see Important Safety Information on pages 12-13 and accompanying full Prescribing Information.



• Swallow XTANDI capsules whole. Do not chew, dissolve, or open the capsules • If you miss a dose of XTANDI, take your prescribed dose as soon as you remember that day. If you miss your daily dose, take your prescribed dose at your regular time the next day. Do not take more than your prescribed dose of XTANDI • If you take too much XTANDI, call your healthcare provider or go to the nearest emergency

• Your doctor may prescribe XTANDI with or without steroids,



## **Important points to remember**

## Take XTANDI (enzalutamide) capsules exactly as prescribed by your doctor.

- The recommended dose of XTANDI is 4 capsules taken once per day
- Getting into a routine can help you remember to take your medicine

## Swallow XTANDI capsules whole with liquid.

• Do not chew, dissolve, or open the capsules

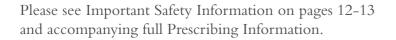
## If you miss a dose of XTANDI, take the missed dose as soon as you remember.

- If you forget for a whole day, take your next dose at your regular time the next day
- Do not take more or less than your prescribed dose of XTANDI per day

## Do NOT stop taking XTANDI without talking with your doctor first.

## How to store XTANDI:

- Store XTANDI between 68°F to 77°F (20°C to 25°C)
- Keep XTANDI capsules dry and in a tightly closed container
- Keep XTANDI and all medicines out of the reach of children







# MOH Ю 5

ΤΑΚΕ XTANDI

## About XTANDI

The effectiveness and safety of XTANDI (enzalutamide) capsules were evaluated in a clinical study. It may help you to know:

- How the study for XTANDI was conducted
- What the study measured
- What the study showed

## How the study was conducted

## **1199 MEN TOOK PART IN THE STUDY**

These men:

- With castration-resistant prostate cancer (prostate cancer that is resistant to medical or surgical treatments that lower testosterone) that has spread to other parts of the body and who had previously received treatment with docetaxel
- · Were being treated with a medicine to lower testosterone OR had been treated with surgery to lower testosterone

800 of these men were given XTANDI

399 of these men were given placebo\*

Patients continued to take XTANDI or placebo until their cancer got worse and they started another medicine.

\*Placebo is a capsule with no active medicine (sugar pill).

Please see Important Safety Information on pages 12-13 and accompanying full Prescribing Information.

## What the study measured

in the study lived.

What the study showed

## MEN TAKING XTANDI LIVED LONGER ON AVERAGE THAN MEN TAKING PLACEBO Median overall survival\* of men in the study Men taking XTANDI Men taking placebo **18.4** months **13.6** months

**Select Safety Information** XTANDI may cause serious side effects, including seizure. Some people have had seizures during treatment with XTANDI (7 of 800 patients in a clinical trial). If you take XTANDI you may be at risk of having a seizure. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others. Tell your healthcare provider right away if you have loss of consciousness or seizure.

\*Median overall survival is the time from the start of treatment until the time when only half of the patients in the study were still alive.

The main objective of the study was to measure overall survival—how long the men



## Possible side effects with XTANDI

Like other cancer medicines, XTANDI (enzalutamide) capsules may cause side effects. It is important to know what side effects may occur so you can talk with your doctor or nurse about them.

## Possible serious side effect

XTANDI may cause serious side effects, including seizure. Some people have had seizures during treatment with XTANDI (7 of 800 patients in a clinical trial). If you take XTANDI you may be at risk of having a seizure. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others. Tell your healthcare provider right away if you have loss of consciousness or seizure.

## Most common side effects

The most common side effects of XTANDI include:

- Weakness or feeling more tired than usual
- Back pain
- Diarrhea
- Pain in your joints
- Hot flashes
- Swelling in your hands, arms, legs or feet
- Muscle or bone pain
- Headache
- Cold like symptoms
- Muscle weakness

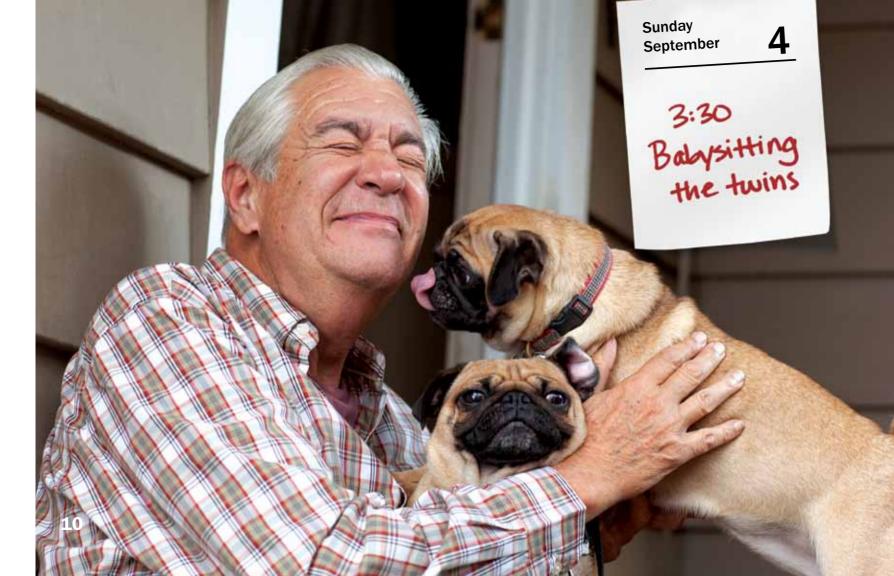
or pharmacist.

For tips to help manage weakness/fatigue, pain (back and joint), diarrhea, and hot flashes, turn to page 15.



- Dizziness
- Trouble falling or staving asleep (insomnia)
- Trouble breathing (pneumonia)
- Back pain with nerve problems in the lower body, including leg numbness or weakness
- Pink or red urine (hematuria)
- Sensation of tingling, burning, pricking, or numbress of skin (paresthesia)
- Anxiety
- High blood pressure (hypertension)
- Tell your doctor if you have any falls or problems thinking clearly. Tell your doctor if you have any side effect that bothers you or that does not go away.
- These are not all the possible side effects of XTANDI. For more information, ask your doctor





# Finding help paying for XTANDI

Your doctor is your main source of information about treatment with XTANDI (enzalutamide) capsules. Your doctor, nurse, or other office staff may have arranged to have your XTANDI prescription filled at a specialty pharmacy (not at a retail pharmacy) or at your doctor's in-office pharmacy. If you are having problems paying for your medicine, first talk with your doctor or nurse. You or your doctor's office can also contact XTANDI Access Services at 1-855-898-2634.

## XTANDI Access Services may find ways to help you pay for XTANDI:

- If you do not have insurance
- If your insurance does not cover XTANDI

XTANDI Access Services<sup>SM</sup> can help you find out what you will be expected to pay and what your insurance covers. This includes coverage with Medicare, Medicaid, private insurance, and TRICARE. You can also get help finding the right specialty pharmacy to fill your XTANDI prescription.

For more information about XTANDI Access Services, call 1-855-8XTANDI (1-855-898-2634) (9 AM to 8 PM eastern time, Monday through Friday) or visit www.XtandiAccessServices.com.

XTANDI Access Services<sup>SM</sup> is a component of Astellas Access Services<sup>SM</sup>.

Please see Important Safety Information on pages 12-13 and accompanying full Prescribing Information.

• If you cannot afford your monthly costs for XTANDI



## **Important Safety Information**

## Who should not take XTANDI?

XTANDI (enzalutamide) capsules is not for use in women. Do not take XTANDI if you are pregnant or may become pregnant. XTANDI may harm your unborn baby. It is not known if XTANDI is safe and effective in children.

## Before you take XTANDI, tell your healthcare provider if you:

- Have a history of seizures, brain injury, stroke, brain tumors.
- Have any other medical conditions.
- Have a partner who is pregnant or plans to become pregnant. Men who are sexually active with a pregnant woman must use a condom during and for 3 months after treatment with XTANDI. If their sexual partner may become pregnant, a condom and another form of birth control must be used during and for 3 months after treatment. Talk with your healthcare provider if you have questions about birth control. See "Who should not take XTANDI?"
- Take any other medicines, including prescription and non-prescription medicines, vitamins, and herbal supplements. XTANDI can interact with many other medicines. You should not start or stop any medicine before you talk with the healthcare provider that prescribed XTANDI.

## How should I take XTANDI?

- Take XTANDI capsules exactly as your healthcare provider tells you.
- Take your prescribed dose of XTANDI one time a day.
- Your healthcare provider may change your dose if needed.
- Do not stop taking your prescribed dose of XTANDI without talking with your healthcare provider first.
- XTANDI capsules can be taken with or without food.
- Swallow XTANDI capsules whole. Do not chew, dissolve, or open the capsules.

- dose of XTANDI
- right away.

## What are the possible side effects of XTANDI? XTANDI may cause serious side effects including:

The most common side effects of XTANDI include weakness or feeling more tired than usual, back pain, diarrhea, pain in your joints, hot flashes, swelling in your hands, arms, legs or feet, muscle or bone pain, headache, cold like symptoms, muscle weakness, dizziness, trouble falling or staying asleep (insomnia), trouble breathing (pneumonia), back pain with nerve problems in the lower body, including leg numbness or weakness, pink or red urine (hematuria), sensation of tingling, burning, pricking, or numbress of skin (paresthesia), anxiety, and high blood pressure (hypertension).

Tell your healthcare provider if you have any falls or problems thinking clearly. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of XTANDI. For more information, ask your healthcare provider or pharmacist.

#### You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the accompanying Full Prescribing Information for complete safety information.

• If you miss a dose of XTANDI, take your prescribed dose as soon as you remember that day. If you miss your daily dose, take your prescribed dose at your regular time the next day. Do not take more than your prescribed

• If you take too much XTANDI, call your healthcare provider or go to the nearest emergency room

• Seizure: Some people have had seizures during treatment with XTANDI. If you take XTANDI you may be at risk of having a seizure. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others. Tell your healthcare provider right away if you have loss of consciousness or seizure.



13



# Tips for managing side effects

You may have side effects while taking XTANDI (enzalutamide) capsules. The following tips may help you manage the 5 most common side effects of treatment with XTANDI— weakness/fatigue, pain (back and joint), diarrhea, and hot flashes.

Remember to talk with your doctor or nurse about your side effects and ways to help manage them.

Tips included on pages 16-23 come from organizations focused on supporting people with cancer. This information is not meant to replace your doctor's advice. Always talk to your doctor about managing side effects.

Please see Important Safety Information on pages 12-13 and accompanying full Prescribing Information.



15

## Managing weakness

Weakness is the loss or lack of body strength. It is a common side effect of XTANDI (enzalutamide) capsules. People with cancer may have weakness for a number of reasons, both physical and mental. Some signs of weakness are:

- Feeling tired
- Having muscle aches and pains
- Finding it hard to change positions, such as from sitting to standing
- Feeling dizzy and having trouble keeping your balance

## Try these tips to manage weakness

## Drink plenty of fluids

• Drink as much liquid as your doctor will allow

## Try to be active

- Do light stretching or range-of-motion exercises
- Take short walks if your doctor allows it
- Try to be active in a way that's safe, especially if you are feeling weak:
- Wear shoes, not slippers (which slide off too easily), when walking or standing
- Use a brace, cane, or walker or other support that your doctor or nurse tells you to
- Change positions at least every 2 hours while sitting; this will relieve pressure

Talk with your doctor about healthy ways to add exercise to your day.

# Managing fatigue (feeling more tired than usual)

You may be experiencing fatigue if you:

- Feel tired and it does not get better, keeps coming back, or becomes severe
- Do not feel better with rest or sleep
- Have trouble concentrating or become confused
- Have no desire to do the things you normally do

## Try these tips to manage fatigue

#### Exercise

## Manage stress

- Talk with other men in support groups
- See a counselor
- Try relaxation exercises

## Have good sleep habits

- Limit naps to under an hour
- tea, and chocolate

- Fatigue, or feeling more tired than usual, is a common side effect of XTANDI.



• Exercise may help you feel better both physically and mentally • Talk with your doctor about healthy ways to add exercise into your day

• Talk with your doctor or nurse if you are feeling stressed

• Try to go to bed and wake up at the same time every day

• Avoid foods and drinks high in caffeine, such as coffee,



## Managing pain

Pain is common in people with cancer. There can be pain from the disease or from your treatment's side effects. Back pain and joint pain (arthralgia) are among the most common side effects of XTANDI (enzalutamide) capsules.

It is important to talk with your doctor or nurse about any pain you are having. He or she will ask questions to find the cause of your pain. Work closely with your doctor or nurse to find ways to help you cope with pain or reduce it. Be sure to always talk with your doctor before trying any pain tip.



## Try these tips to manage pain

#### Keep a journal with details about your pain to share with your doctor:

- Write down the day and time you had pain and how long it lasted; also note what you were doing when the pain started
- Describe where the pain started and if it stayed in one area or spread to other parts of the body
- Give your pain a number on a scale of 0 to 10, with 10 being the highest level of pain
- Use words that describe the pain, such as *burning*, *stabbing*, or *throbbing*
- Keep track of the types of pain relief you tried and how they worked

## Managing pain (cont'd)

#### Try to exercise

creating an exercise plan that's best for you

## Try compresses

## Try relaxation techniques

to help reduce tension and decrease pain

are having.

• Talk with your doctor about healthy ways to add exercise to your day and about

• Use warm compresses to reduce pain, especially if it is muscle related

• Use relaxation techniques, such as breathing exercises and meditation,

Talk with your doctor about medicines that may help decrease your pain • He or she may prescribe certain medicines to help reduce your pain

Work closely with your doctor or nurse to help manage any pain you



## Managing diarrhea

Diarrhea is when you have 2 or more loose or watery stools in 4 hours. It is a common side effect in patients taking XTANDI (enzalutamide) capsules. Talk with your doctor or nurse if diarrhea lasts more than 24 hours or if you also have pain or cramping. There are some things you can do to help manage diarrhea.

## Try these tips to manage diarrhea

#### Drink plenty of fluids

- Stick to mild, clear liquids, such as apple juice, water, or clear broth
- Drink slowly, and keep fluids at room temperature

## Eat smaller amounts of food, but eat more often. Avoid foods that can make diarrhea worse. These include:

- Coffee, tea, alcohol, and sweets
- High-fiber foods, such as whole-grain breads, raw vegetables, and fresh and dried fruit
- Fried, greasy, or spicy foods
- Milk and other dairy products

Talk with your doctor or nurse about medicines that can help control diarrhea.

Please see Important Safety Information on pages 12-13 and accompanying full Prescribing Information.

## Managing hot flashes

A hot flash is a sudden and brief feeling of body warmth and sweating. It is a common side effect of XTANDI. Some ways to help you manage hot flashes are listed below.

## Try these tips to manage hot flashes

Try to lower your body's temperature.

- Wear loose-fitting cotton clothing
- Use fans and open windows to keep air moving
- Try relaxation techniques, such as slow, deep breathing

21

- Talk with your doctor or nurse about medicines to help control hot flashes.







## Take an active role in your care

Your cancer care involves a team of people. As part of that team, YOU are in charge of taking your medicine. To get the most out of your treatment with XTANDI (enzalutamide) capsules, you need to take it exactly as your healthcare team tells you.

## Stay on track

them to help you.

## The following tips may also help you stay on track with XTANDI:

# Take XTANDI at the same time every day to make it a routine.

- Use a calendar or tracker
- appointments are
- The XTANDI calendar at the end of this brochure is a great way to help you keep track Keep your medicine in a pillbox.

- Using a pillbox helps you organize, by day, your XTANDI capsules and any other medicines you take and lets you know if you took each day's dose • Keep capsules dry and in a tightly closed container
- Make reminders.
- Set an alarm or a daily reminder on your cell phone • Leave yourself a note in a place you will see every day

You may find it hard to stick with treatment sometimes. It is important to take note of what may be causing you trouble. Talk with your doctor or nurse about it. Being open can make it easier for

- Record when to take your medicine, when to order more, and when your healthcare





## Living with prostate cancer

There are many resources that can help you learn about living with prostate cancer. These may include cancer organizations and government agencies. They can provide information, in-person help, or support over the phone.

## Resources

#### Prostate cancer organizations

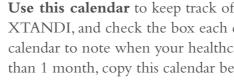
- Prostate Cancer Foundation www.pcf.org
- Prostate Cancer Research Institute www.prostate-cancer.org
- Us TOO International www.ustoo.org
- The Prostate Health Education Network (PHEN) www.prostatehealthed.org
- ZERO www.zerocancer.org

#### General cancer resources

- American Cancer Society www.cancer.org
- Cancer*Care* www.cancercare.org
- National Cancer Institute www.cancer.gov
- National Coalition for Cancer Survivorship www.canceradvocacy.org

#### Additional helpful resources

- www.MyLifeline.org
- www.mypillbox.org

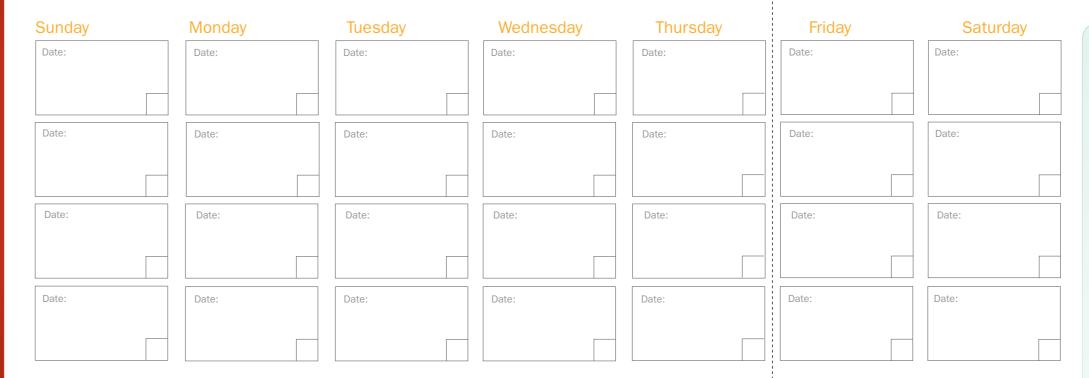


alendar

Ö

Treatment

XTANDI



Please see Important Safety Information on pages 12-13 and accompanying full Prescribing Information.

Please see Important Safety Information on pages 12-13 and accompanying full Prescribing Information.

Use this calendar to keep track of your XTANDI (enzalutamide) capsules therapy. Write in the date you start XTANDI, and check the box each day 📝 after you take your medicine as prescribed. You can also use this calendar to note when your healthcare appointments are scheduled and when to order refills. To track more than 1 month, copy this calendar before using it, or download it at www.AboutXtandi.com.

Notes to share with your healthcare team.



It is important to take XTANDI capsules exactly as your healthcare provider tells you.

- Take your prescribed dose of XTANDI once a day
- Your healthcare provider may change your dose if needed
- Do not stop taking your prescribed dose of XTANDI without talking with your healthcare provider first
- XTANDI capsules can be taken with or without food
- Swallow XTANDI capsules whole. Do not chew, dissolve, or open the capsules
- If you miss a dose of XTANDI, take your prescribed dose as soon as you remember that day
- If you miss your daily dose, take your prescribed dose at your regular time the next day. Do not take more than your prescribed dose of XTANDI
- If you take too much XTANDI, call your healthcare provider or go to the nearest emergency room right away

Always talk with your doctor if you have any questions or concerns about your treatment with XTANDI.



## Medicine reminder mobile apps iPhone

- Remind Me Available at www.apple.com/itunes Android phone
- Pillbox Alert www.pillboxalert.com

## Care partner resources

- Family Caregiver Alliance www.caregiver.org
- Lotsa Helping Hands www.lotsahelpinghands.org

## Caregiver mobile apps

- Caregiver.com www.appsforall.net/1/Caregiver\_Page.html
- CareConnector

www.caregiving.com/2010/06/iphone-apps-for-caregivers

Astellas and Medivation are not affiliated with and do not endorse any of the listed organizations or resources. The information provided by Astellas and Medivation is for informational purposes only and is not meant to replace a doctor's or nurse's advice.



# **XTANDI Access Services**

Your doctor is your main source of information about treatment with XTANDI (enzalutamide) capsules. Your doctor, nurse, or office staff may have arranged to have your XTANDI prescription filled at a specialty pharmacy or at your doctor's in-office pharmacy. If you are having problems paying for your medicine, first talk with your doctor or nurse. You can also contact XTANDI Access Services at 1-855-898-2634.

## XTANDI Access Services may find ways to help you pay for XTANDI:

- If you do not have insurance
- If your insurance does not cover XTANDI
- If you cannot afford your monthly costs for XTANDI

XTANDI Access Services<sup>SM</sup> can help you find out what you will be expected to pay and what your insurance covers. This includes coverage with Medicare, Medicaid, private insurance, and TRICARE. You can also get help finding a specialty pharmacy to fill your XTANDI prescription.

For more information about XTANDI Access Services. call 1-855-8XTANDI (1-855-898-2634) (9 AM to 8 PM eastern time, Monday through Friday) or visit www.XtandiAccessServices.com.

XTANDI Access Services<sup>SM</sup> is a component of Astellas Access Services<sup>SM</sup>.

26

#### Package Insert Here

If you have questions about your treatment, talk with your doctor. You can also visit AboutXTANDI.com for more information. If you're getting XTANDI from a specialty pharmacy, write its contact information in the space provided below.

Your specialty	pharmacy	information
Pharmacist name:		

Pharmacy name:

Pharmacy phone number.

Pharmacy hours: \_





Report side effects to FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.

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