Package leaflet: Information for the user

SUSTIVA 50 mg hard capsules
SUSTIVA 100 mg hard capsules
SUSTIVA 200 mg hard capsules
efavirenz

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What SUSTIVA is and what it is used for

SUSTIVA, which contains the active substance efavirenz, belongs to a class of antiretroviral medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs). It is an **antiretroviral medicine that fights human immunodeficiency virus** (HIV-1) infection by reducing the amount of the virus in blood. It is used by adults, adolescents and children 3 months of age and older and weighing at least 3.5 kg.
Your doctor has prescribed SUSTIVA for you because you have HIV infection.
SUSTIVA taken in combination with other antiretroviral medicines reduces the amount of the virus in the blood. This will strengthen your immune system and reduce the risk of developing illnesses linked to HIV infection.

2. What you need to know before you take SUSTIVA

Do not take SUSTIVA
- **if you are allergic** to efavirenz or any of the other ingredients of this medicine (listed in section 6). Contact your doctor or pharmacist for advice.

- **if you have severe liver disease.**

- **if you have a heart condition, such as changes in the rhythm or rate of the heart beat, a slow heart beat, or severe heart disease.**

- if any member of your family (parents, grandparents, brothers or sisters) has died suddenly due to a heart problem or was born with heart problems.

- if your doctor has told you that you have high or low levels of electrolytes such as potassium or magnesium in your blood.

- **if you are currently taking** any of the following medicines (see also "Other medicines and Sustiva"):
  - **astemizole or terfenadine** (used to treat allergy symptoms)
  - **bepridil** (used to treat heart disease)
  - **cisapride** (used to treat heartburn)
  - **ergot alkaloids** (for example, ergotamine, dihydroergotamine, ergonovine, and methylergonovine) (used to treat migraine and cluster headaches)
  - **midazolam or triazolam** (used to help you sleep)
  - **pimozide, imipramine, amitriptyline or clomipramine** (used to treat certain mental conditions)
  - **elbasvir or grazoprevir** (used to treat hepatitis C)
  - **St. John's wort** (*Hypericum perforatum*) (a herbal remedy used for depression and anxiety)
  - **flecainide, metoprolol** (used to treat irregular heart beat)
  - **certain antibiotics** (macrolides, fluoroquinolones, imidazole)
  - **triazole antifungal agents**
  - certain **antimalarial treatments**
  - methadone (used to treat opiate addiction)

  If you are taking any of these medicines, tell your doctor immediately. Taking these medicines with SUSTIVA could create the potential for serious and/or life-threatening side-effects or stop SUSTIVA from working properly.

Warnings and precautions
Talk to your doctor before taking SUSTIVA

- **SUSTIVA must be taken with other medicines that act against the HIV virus.** If SUSTIVA is started because your current treatment has not prevented the virus from multiplying, another medicine you have not taken before must be started at the same time.

- **You can still pass on HIV** when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people. This medicine is not a cure for HIV infection and you may continue to develop infections or other illnesses associated with HIV disease.

- You must remain under the care of your doctor while taking SUSTIVA.

- **Tell your doctor:**

  - **if you have a history of mental illness,** including depression, or of substance or alcohol abuse. Tell your doctor immediately if you feel depressed, have suicidal thoughts or have strange thoughts (see section 4, *Possible side effects*).

  - **if you have a history of convulsions (fits or seizures)** or if you are being treated with anticonvulsant therapy such as carbamazepine, phenobarbital and phenytoin. If you are taking any of these medicines, your doctor may need to check the level of anticonvulsant medicine in your blood to ensure that it is not affected while taking SUSTIVA. Your doctor may give you a different anticonvulsant.

- **if you have a history of liver disease, including active chronic hepatitis**. Patients with chronic hepatitis B or C and treated with combination antiretroviral agents have a higher risk for severe and potentially life-threatening liver problems. Your doctor may conduct blood tests in order to check how well your liver is working or may switch you to another medicine. **If you have severe liver disease, do not take SUSTIVA** (see section 2, *Do not take SUSTIVA*).

- **if you have a heart disorder, such as abnormal electrical signal called prolongation of the QT interval.**

- **Once you start taking SUSTIVA, look out for:**

  - **signs of dizziness, difficulty sleeping, drowsiness, difficulty concentrating or abnormal dreaming.** These side effects may start in the first 1 or 2 days of treatment and usually go away after the first 2 to 4 weeks.

  - **any signs of skin rash.** If you see any signs of a severe rash with blistering or fever, stop taking SUSTIVA and tell your doctor at once. If you had a rash while taking another NNRTI, you may be at a higher risk of getting a rash with SUSTIVA.

  - **any signs of inflammation or infection**. In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please tell your doctor immediately.
    In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

  - **bone problems.** Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your doctor.

Children and adolescents
SUSTIVA is not recommeded for children under the age of 3 months or weighing less than 3.5 kg because it has not been adequately studied in these patients.

Other medicines and SUSTIVA
You must not take SUSTIVA with certain medicines. These are listed under Do not take SUSTIVA, at the start of Section 2. They include some common medicines and a herbal remedy (St. John's wort) which can cause serious interactions.

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

SUSTIVA may interact with other medicines, including herbal preparations such as *Ginkgo biloba* extracts. As a result, the amounts of SUSTIVA or other medicines in your blood may be affected. This may stop the medicines from working properly, or may make any side effects worse. In some cases, your doctor may need to adjust your dose or check your blood levels. **It is important to tell your doctor or pharmacist if you are taking any of the following:**

- **Other medicines used for HIV infection**:
  - protease inhibitors: darunavir, indinavir, lopinavir/ritonavir, ritonavir, ritonavir boosted atazanavir, saquinavir or fosamprenavir/saquinavir. Your doctor may consider giving you an alternative medicine or changing the dose of the protease inhibitors.
  - maraviroc
  - the combination tablet containing efavirenz, emtricitabine, and tenofovir should not be taken with SUSTIVA unless recommended by your doctor since it contains efavirenz, the active ingredient of SUSTIVA.

- **Medicines used to treat infection with the hepatitis C virus:** boceprevir, telaprevir, elbasvir/grazoprevir, simeprevir, sofosbuvir/velpatasvir, sofosbuvir/velpatasvir/voxilaprevir, glecaprevir/pibrentasvir.

- **Medicines used to treat bacterial infections**, including tuberculosis and AIDS-related mycobacterium avium complex: clarithromycin, rifabutin, rifampicin. Your doctor may consider changing your dose or giving you an alternative antibiotic. In addition, your doctor may prescribe a higher dose of SUSTIVA.

- **Medicines used to treat fungal infections (antifungals):**
  - voriconazole. SUSTIVA may reduce the amount of voriconazole in your blood and voriconazole may increase the amount of SUSTIVA in your blood. If you take these two medicines together, the dose of voriconazole must be increased and the dose of efavirenz must be reduced. You must check with your doctor first.
  - itraconazole. SUSTIVA may reduce the amount of itraconazole in your blood.
  - posaconazole. SUSTIVA may reduce the amount of posaconazole in your blood.

- **Medicines used to treat malaria:**
  - artemether/lumefantrine: SUSTIVA may reduce the amount of artemether/lumefantrine in your blood.
  - atovaquone/proguanil: SUSTIVA may reduce the amount of atovaquone/proguanil in your blood.

- **Medicines used to treat convulsions/seizures (anticonvulsants):** carbamazepine, phenytoin, phenobarbital. SUSTIVA can reduce or increase the amount of anticonvulsant in your blood. Carbamazepine may make SUSTIVA less likely to work. Your doctor may need to consider giving you a different anticonvulsant.

- **Medicines used to lower blood fats (also called statins):** atorvastatin, pravastatin, simvastatin. SUSTIVA can reduce the amount of statins in your blood. Your doctor will check your cholesterol levels and will consider changing the dose of your statin, if needed.

- **Methadone** (a medicine used to treat opiate addiction): your doctor may recommend an alternative treatment.

- **Sertraline** (a medicine used to treat depression): your doctor may need to change your dose of sertraline.

- **Bupropion** (a medicine used to treat depression or to help you stop smoking): your doctor may need to change your dose of bupropion.

- **Diltiazem or similar medicines (called calcium channel blockers which are medicines typically used for high blood pressure or heart problems):** when you start taking SUSTIVA, your doctor may need to adjust your dose of the calcium channel blocker.

- **Immunosuppressants such as cyclosporine, sirolimus, or tacrolimus** (medicines used to prevent organ transplant rejection)**:** when you start or stop taking SUSTIVA, your doctor will closely monitor your plasma levels of the immunosuppressant and may need to adjust its dose.

- **Hormonal contraceptive, such as birth control pills, an injected contraceptive (for example, Depo-Provera), or a contraceptive implant (for example, Implanon)**: you must also use a reliable barrier method of contraception (see Pregnancy,breast-feeding and fertility). SUSTIVA may make hormonal contraceptives less likely to work. Pregnancies have occurred in women taking SUSTIVA while using a contraceptive implant, although it has not been established that the SUSTIVA therapy caused the contraceptive to fail.

- **Warfarin** or acenocoumarol (medicines used to reduce clotting of the blood): your doctor may need to adjust your dose of warfarin or acenocoumarol.

- *Ginkgo biloba* extracts (a herbal preparation)

- **Medicines that impact heart rhythm:**
  - **Medicines used to treat heart rhythm problems:** such as flecainide or metoprolol.
  - **Medicines used to treat depression** such as imipramine, amitriptyline or clomipramine
  - **Antibiotics**, including the following types: macrolides, fluoroquinolones or imidazole.

SUSTIVA with food and drink
Taking SUSTIVA on an empty stomach may reduce the undesirable effects. Grapefuit juice should be avoided when taking SUSTIVA.

Pregnancy and breast-feeding
Women should not get pregnant during treatment with SUSTIVA, and for **12 weeks thereafter.** Your doctor may require you to take a pregnancy test to ensure you are not pregnant before starting treatment with SUSTIVA.

If you could get pregnant while receiving SUSTIVA, you need to use a reliable form of barrier contraception (for example, a condom) with other methods of contraception including oral (pill) or other hormonal contraceptives (for example, implants, injection). Efavirenz may remain in your blood for a time after therapy is stopped. Therefore, you should continue to use contraceptive measures, as above, for 12 weeks after you stop taking SUSTIVA.

Tell your doctor immediately if you are pregnant or intend to become pregnant. If you are pregnant, you should take SUSTIVA only if you and your doctor decide it is clearly needed. Ask your doctor or pharmacist for advice before taking any medicine.

Serious birth defects have been seen in unborn animals and in the babies of women treated with efavirenz or a combination medicine containing efavirenz, emtricitabine and tenofovir during pregnancy. If you have taken SUSTIVA or the combination tablet containing efavirenz, emtricitabine, and tenofovir during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child.

You should not breast feed your baby if you are taking SUSTIVA.

Driving and using machines
SUSTIVA contains efavirenz and may cause dizziness, impaired concentration, and drowsiness. If you are affected, do not drive and do not use any tools or machines.

SUSTIVA contains lactose in each 600-mg daily dose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take SUSTIVA

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will give you instructions for proper dosing.

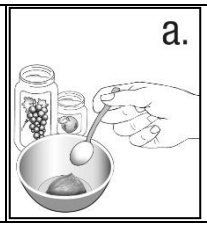
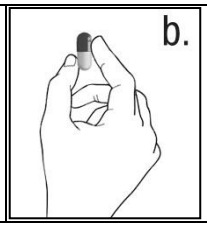
- The dose for adults is 600 mg once daily.
- The dose for SUSTIVA may need to be increased or decreased if you are also taking certain medicines (see Other medicines and SUSTIVA).
- SUSTIVA is for oral use. SUSTIVA is recommended to be taken on an empty stomach preferably at bedtime. This may make some side effects (for example, dizziness, drowsiness) less troublesome. An empty stomach is commonly defined as 1 hour before or 2 hours after a meal.
- It is recommended that the capsule be swallowed whole with water.
- SUSTIVA must be taken every day.
- SUSTIVA should never be used alone to treat HIV. SUSTIVA must always be taken in combination with other anti-HIV medicines.

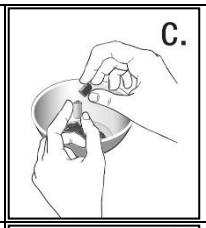
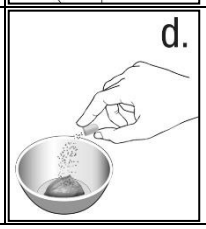
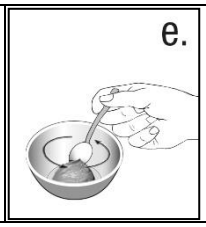
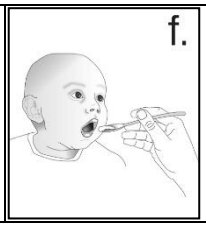
Use in children and adolescents
- SUSTIVA hard capsules can be taken by children and adolescents 3 months of age and older and weighing at least 3.5 kg who are able to swallow the capsules. Opening the capsule and taking the contents with a small amount of food may be considered for children who cannot swallow the hard capsule.
- The dose for children and adolescents is calculated by body weight and is taken once daily as shown below:

Body Weight kg	SUSTIVA Dose (mg)	Number of Capsules or Tablets and Strength to Administer
3.5 to < 5	100	one 100 mg capsule
5 to < 7.5	150	one 100 mg capsule + one 50 mg capsule
7.5 to < 15	200	one 200 mg capsule
15 to < 20	250	one 200 mg capsule + one 50 mg capsule
20 to < 25	300	three 100 mg capsules
25 to < 32.5	350	three 100 mg capsules + one 50 mg capsule
32.5 to < 40	400	two 200 mg capsules
≥ 40	600	one 600 mg tablet OR three 200 mg capsules

For children who are not able to swallow the capsules, the doctor may recommend opening the hard capsule and mixing the contents with a small amount (1-2 teaspoons) of food (e.g., yogurt). The capsules must be opened carefully so that the contents do not spill or escape into the air. Hold the capsule with the cap facing up and pull the cap away from the body of the capsule. Use a small container for mixing. Give the mixture to the child as soon as possible, but no more than 30 minutes after mixing. Make sure the child eats the full amount of the mixture of food and capsule contents. Add another small amount (approximately 2 teaspoons) of the food to the empty mixing container, stirring to make sure there is no drug residue remaining in the container, and have the child eat the full amount again. The child should not be given any additional food for 2 hours. The doctor may also recommend this method of taking SUSTIVA for adults who cannot swallow capsules.

Instructions for capsule sprinkle method:

1	Avoid giving the daily SUSTIVA dose within 1 hour after a feeding or meal.	
2	Wash and dry your hands before and after preparing the capsule sprinkle.	
3	Choose a soft food the child likes. Examples of soft foods are applesauce, grape jelly, yogurt, or infant formula. In a taste preference study in adults, SUSTIVA mixed with grape jelly received the best rating.	
4	Place 1-2 teaspoons of the food in a small container (illustration a).	
5	**SUSTIVA capsules must be opened carefully over the food container**, as described in steps 6-7, **so that the contents do not spill**.	
6	With your hands over the container, hold the capsule with the cap facing up (see illustration b).	

7	Carefully pull the cap away from the body of the capsule (illustration c).	
8	Sprinkle the contents of the capsule on the food (illustration d).	
9	If the daily dose consists of more than one capsule, follow steps 5-8 for each capsule. **Do not** add more food.	
10	Mix the capsule contents and food together (illustration e).	
Steps 11-14 must be completed within 30 minutes of mixing:		
11	Give the mixture of food and capsule contents to the child, making sure he or she eats the full amount (illustration f).	
12	Add another small amount (approximately 2 teaspoons) of the food to the empty mixing container (illustration a).	
13	Stir to make sure there is no drug residue remaining in the container (illustration e).	
14	Have the child eat the full amount again (illustration f).	
15	**Do not give the child any additional food for 2 hours.**	

If you take more SUSTIVA than you should
If you take too much SUSTIVA contact your doctor or nearest emergency department for advice. Keep the medicine container with you so that you can easily describe what you have taken.

If you forget to take SUSTIVA
Try not to miss a dose. **If you do miss a dose,** take the next dose as soon as possible, but do not take a double dose to make up for a forgotten dose. If you need help in planning the best times to take your medicine, ask your doctor or pharmacist.

If you stop taking SUSTIVA
When your SUSTIVA supply starts to run low, get more from your doctor or pharmacist. This is very important because the amount of virus may start to increase if the medicine is stopped for even a short time. The virus may then become harder to treat.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
When treating HIV infection, it is not always possible to tell whether some of the unwanted effects are caused by SUSTIVA or by other medicines that you are taking at the same time, or by the HIV disease itself.

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

The most notable unwanted effects reported with SUSTIVA in combination with other anti-HIV medicines are skin rash and nervous system symptoms.

You should consult your doctor if you have a rash, since some rashes may be serious; however, most cases of rash disappear without any change to your treatment with SUSTIVA. Rash was more common in children than in adults treated with SUSTIVA.

The nervous system symptoms tend to occur when treatment is first started, but generally decrease in the first few weeks. In one study, nervous system symptoms often occurred during the first 1-3 hours after taking a dose. If you are affected your doctor may suggest that you take SUSTIVA at bedtime and on an empty stomach. Some patients have more serious symptoms that may affect mood or the ability to think clearly. Some patients have actually committed suicide. These problems tend to occur more often in those who have a history of mental illness. Always notify your doctor immediately if you have these symptoms or any side effects while taking SUSTIVA.

Tell your doctor if you notice any of the following side effects:

Very common (affects more than 1 user in 10)
- skin rash

Common (affects 1 to 10 users in 100)
- abnormal dreams, difficulty concentrating, dizziness, headache, difficulty sleeping, drowsiness, problems with coordination or balance
- stomach pain, diarrhoea, feeling sick (nausea), vomiting
- itching
- tiredness
- feeling anxious, feeling depressed

Tests may show:
- increased liver enzymes in the blood
- increased trigycerides (fatty acids) in the blood

Uncommon (affects 1 to 10 users in 1,000)
- nervousness, forgetfulness, confusion, fitting (seizures), abnormal thoughts
- blurred vision
- a feeling of spinning or tilting (vertigo)
- pain in the abdomen (stomach) caused by inflammation of the pancreas
- allergic reaction (hypersensitivity) that may cause severe skin reactions (erythema multiforme, Stevens-Johnson syndrome)
- yellow skin or eyes, itching, or pain in the abdomen (stomach) caused by inflammation of the liver

- breast enlargement in males
- angry behaviour, mood being affected, seeing or hearing things that are not really there (hallucinations), mania (mental condition characterised by episodes of overactivity, elation or irritability), paranoia, suicidal thoughts, catatonia (condition in which the patient is rendered motionless and speechless for a period)
- whistling, ringing or other persistent noise in the ears
- tremor (shaking)
- flushing

Tests may show:
- increased cholesterol in the blood

Rare (affects 1 to 10 users in 10,000)
- itchy rash caused by a reaction to sunlight
- liver failure, in some cases leading to death or liver transplant, has occurred with efavirenz. Most cases occurred in patients who already had liver disease, but there have been a few reports in patients without any existing liver disease.
- unexplained feelings of distress not associated with hallucinations, but it may be difficult to think clearly or sensibly
- suicide

Reporting of side effects
If you get any 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 directly via (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

1. IRELAND
HPRA Pharmacovigilance Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

2. MALTA
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

3. UNITED KINGDOM
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store SUSTIVA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle or blister and on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What SUSTIVA 50 mg contains
- Each SUSTIVA hard capsule contains 50 mg of the active substance efavirenz.
- The other ingredients of the powder contained in the hard capsule are: sodium laurilsulfate, lactose monohydrate, magnesium stearate and sodium starch glycolate.
- The capsule shell contains: gelatine, sodium laurilsulfate, yellow iron oxide (E172), titanium dioxide (E171) and silicon dioxide.
- The capsules are printed with inks containing cochineal carminic acid (E120), indigo carmine (E132), and titanium dioxide (E171).

What SUSTIVA 100 mg contains
- Each SUSTIVA hard capsule contains 100 mg of the active substance efavirenz.
- The other ingredients of the powder contained in the hard capsule are: sodium laurilsulfate, lactose monohydrate, magnesium stearate and sodium starch glycolate.
- The capsule shell contains: gelatine, sodium laurilsulfate, titanium dioxide (E171) and silicon dioxide.
- The capsules are printed with inks containing cochineal carminic acid (E120), indigo carmine (E132), and titanium dioxide (E171).

What SUSTIVA 200 mg contains
- Each SUSTIVA hard capsule contains 200 mg of the active substance efavirenz.
- The other ingredients of the powder contained in the hard capsule are: sodium laurilsulfate, lactose monohydrate, magnesium stearate and sodium starch glycolate.
- The capsule shell contains: gelatine, sodium laurilsulfate, yellow iron oxide (E172) and silicon dioxide.
- The capsules are printed with inks containing cochineal carminic acid (E120), indigo carmine (E132), and titanium dioxide (E171).

What SUSTIVA looks like and contents of the pack
SUSTIVA 50 mg and 100 mg hard capsules are supplied in bottles of 30 capsules.
SUSTIVA 200 mg hard capsules are supplied in bottles of 90 capsules and in packs containing 42 x 1 capsules in aluminium/PVC perforated unit dose blisters. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Bristol-Myers Squibb Pharma EEIG
Plaza 254
Blanchardstown Corporate Park 2
Dublin 15
D15 T867
Ireland

Manufacturer
Bristol-Myers Squibb S.r.l.
Contrada Fontana del Ceraso
03012 Anagni (FR)
Italy

Aesica Queenborough Limited
North Road, Queenborough
Kent, ME11 5EL
United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Belgique/België/Belgien
MSD Belgium BVBA/SPRL
Tél/Tel: 0800 38 693 (+32(0)27766211)
dpoc_belux@merck.com

България
Мерк Шарп и Доум България ЕООД
Тел.: +359 2 819 3737
info-msdbg@merck.com

Česká republika
Merck Sharp & Dohme s.r.o.
Tel.: +420 233 010 111
dpoc_czechslovak @merck.com

Danmark
MSD Danmark ApS
Tlf: +45 44 82 40 00
dkmail@merck.com

Deutschland
Bristol-Myers Squibb GmbH & Co. KGaA
Tel: +49 89 121 42-0

Eesti
Merck Sharp & Dohme OÜ
Tel.: +372 6144 200
msdeesti@merck.com

Ελλάδα
MSD Α.Φ.Β.Ε.Ε
Τηλ: + 30-210 98 97 300
dpoc_greece@merck.com

España
Bristol-Myers Squibb, S.A.
Tel: +34 91 456 53 00

Lietuva
UAB Merck Sharp & Dohme
Tel.: +370 5 278 02 47
msd_lietuva@merck.com

Luxembourg/Luxemburg
MSD Belgium BVBA/SPRL
Tél/Tel: +32(0)27766211
dpoc_belux@merck.com

Magyarország
MSD Pharma Hungary Kft.
Tel.: +361 888 53 00
hungary_msd@merck.com

Malta
Merck Sharp & Dohme Cyprus Limited
Tel: 8007 4433 (+356 99917558)
malta_info@merck.com

Nederland
Merck Sharp & Dohme BV
Tel: 0800 9999000 (+31 23 5153153)
medicalinfo.nl@merck.com

Norge
MSD (Norge) AS
Tlf: +47 32 20 73 00
msdnorge@msd.no

Österreich
Merck Sharp & Dohme Ges.m.b.H.
Tel: +43 (0) 1 26 044
msd-medizin@merck.com

Polska
MSD Polska Sp. z o.o.
Tel.: +48 22 549 51 00
msdpolska@merck.com

France
Bristol-Myers Squibb Sarl.
Tél: +33 (0)1 58 83 84 96

Hrvatska
Merck Sharp & Dohme d.o.o.
Tel: + 385 1 6611 333
croatia_info@merck.com

Ireland
Bristol-Myers Squibb Pharmaceuticals Ltd
Tel: + 353 (1 800) 749 749

Ísland
Vistor hf.
Sími: +354 535 7000

Italia
Bristol-Myers Squibb S.r.l.
Tel: +39 06 50 39 61

Κύπρος
Merck Sharp & Dohme Cyprus Limited
Τηλ: 80000 673 (+357 22866700)
cyprus_info@merck.com

Latvija
SIA Merck Sharp & Dohme Latvija
Tel: +371 67364 224
msd_lv@merck.com

Portugal
Merck Sharp & Dohme, Lda
Tel: +351 21 4465700
clic@merck.com

România
Merck Sharp & Dohme Romania S.R.L.
Tel: + 4021 529 29 00
msdromania@merck.com

Slovenija
Merck Sharp & Dohme, inovativna zdravila d.o.o.
Tel: + 386 1 5204201
msd_slovenia@merck.com

Slovenská republika
Merck Sharp & Dohme, s. r. o.
Tel.: +421 2 58282010
dpoc_czechslovak @merck.com

Suomi/Finland
MSD Finland Oy
Puh/Tel: +358 (0) 9 804650
info@msd.fi

Sverige
Merck Sharp & Dohme (Sweden) AB
Tel: +46 (0)77 5700488
medicinskinfo@merck.com

United Kingdom
Bristol-Myers Squibb Pharmaceuticals Ltd.
Tel: +44 (0800) 731 1736

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu