PACKAGE LEAFLET

Package leaflet: Information for the user

Azacitidine Teva 200 mg, filmomhulde tabletten
Azacitidine Teva 300 mg, filmomhulde tabletten
azacitidine

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

1. What [Product name] is and what it is used for

What [Product name] is
[Product name] is an anti-cancer medicine that belongs to a group of medicines called anti-metabolites. [Product name] contains the active substance azacitidine.

What [Product name] is used for
[Product name] is used to treat adults with acute myeloid leukaemia (AML). This is a form of cancer which affects your bone marrow and can cause problems with producing normal blood cells.
[Product name] is used to keep the disease in control (remission, when the disease is less severe or not active).

How [Product name] works
[Product name] works by preventing cancer cells from growing. Azacitidine, the active substance in [Product name], works by altering the way the cell turns genes on and off. It also reduces the production of new genetic material (RNA and DNA). These effects are thought to block growth of cancer cells in leukaemia.

Talk to your doctor or nurse if you have any questions about how [Product name] works or why this medicine has been prescribed for you.

2. What you need to know before you take [Product name]

Do not take [Product name]
- if you are allergic to azacitidine or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding.

Warnings and precautions

Blood tests
You will have blood tests before you begin treatment with [Product name] and during treatment with [Product name] to check that you have enough blood cells and that your liver and kidneys are working properly. Your doctor will decide how often you have blood tests.

Tell your doctor, pharmacist or nurse straight away if you get any of these symptoms during treatment with [Product name]:
- bruising or bleeding - this could be due to a low count of blood cells called platelets;
- fever - this could be due to an infection as a result of having low levels of white blood cells, which can be life-threatening;
- diarrhoea, vomiting or nausea (feeling sick).

Azacitidine can cause a serious immune reaction called 'differentiation syndrome'(see section 4 'Possible side effects').

Your doctor may need to change the dose, interrupt treatment or stop treatment with [Product name] completely. The doctor may prescribe other medicines to help manage these symptoms (see section 3 'How to take [Product name]').

Children and adolescents
[Product name] is not recommended for use in children and adolescents below the age of 18.

Other medicines and [Product name]
Tell your doctor if you are taking, have recently taken or might take any other medicines. This is because [Product name] may affect the way some other medicines work. Also, some other medicines may affect the way [Product name] works.

Pregnancy, contraception and breast-feeding
If you are pregnant or breast-feeding, you think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Men should not father a child while receiving treatment with [Product name].

Pregnancy
Do not take [Product name] during pregnancy as it may be harmful to your baby. Tell your doctor straight away if you become pregnant during treatment.

Contraception
If you are a woman who can become pregnant you should use an effective method of contraception while taking [Product name] and for 6 months after stopping treatment with [Product name]. Men should use an effective method of contraception while taking [Product name] and for 3 months after stopping treatment with [Product name].
Your doctor will discuss with you the most suitable method of contraception for you to use.

Breast-feeding
Do not breast-feed while taking [Product name] as it may be harmful to your child (see section 2 'Do not take [Product name]').

Fertility
[Product name] may affect your ability to have a baby. Talk to your doctor for advice before using it.

Driving and using machines
You may feel tired, weak or have trouble concentrating. If this happens to you or if you have other side effects, do not drive or use any machines or tools.

[Product name] contains lactose
[Product name] contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

[Product name] contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

[Product name] contains Sunset Yellow FCF (E 110)
This medicine contains colouring agent Sunset Yellow FCF (E 110) which may cause allergic reactions.

3. How to take [Product name]

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

How much to take
- The recommended dose is 300 mg taken by mouth once daily.
- Your doctor may reduce your dose to 200 mg once daily in the events of adverse reactions.

[Product name] is given in treatment cycles of 28 days.
- You take [Product name] every day for the first 14 days of each 28-day cycle.
- This is followed by a treatment-free period of 14 days for the rest of the cycle.

Your doctor will tell you what dose of [Product name] to take. The doctor may decide to:
- extend your treatment beyond 14 days in each treatment cycle
- lower your dose or temporarily stop treatment
- reduce your treatment to 7 days.

Always take [Product name] as prescribed by your doctor.

Your doctor will give you a medicine that helps to reduce nausea (feeling sick) and vomiting. You take it 30 minutes before each [Product name] tablet, during your first and second treatment cycles. Your doctor will tell you to take it for a longer period, if you need it.

Taking this medicine
- Take [Product name] once a day - at the same time each day.
- Swallow the tablets whole with a full glass of water.
- To make sure you get the right dose, do not break, crush, dissolve or chew the tablets.
- You can take the medicine with food or between meals.

If you vomit after taking a tablet, do not take another dose on the same day. Instead, wait till the next day and take your next scheduled dose then. Do not take two doses on the same day.

If powder from a broken tablet touches your skin, wash the skin straight away and thoroughly with soap and water. If the powder gets into your eyes, nose or mouth, flush the area thoroughly with water.

If you take more [Product name] than you should
If you take more tablets than you should, contact your doctor or go to a hospital straightaway. If possible, take the medicine pack and this leaflet with you.

If you forget to take [Product name]
If you forget to take [Product name] at the usual time, take your usual dose as soon as you remember on the same day and take your next dose at the usual time the next day. Do not take a double dose to make up for a forgotten or vomited tablet.

If you stop taking [Product name]
Do not stop taking [Product name] unless your doctor tells you to.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Tell your doctor, pharmacist or nurse straight away if you get any of these symptoms during treatment with [Product name]:

Very common: may affect more than 1 in 10 people
- bruising or bleeding - this could be due to a low count of blood cells called platelets;
- fever - this could be due to an infection as a result of having low levels of white blood cells, which can be life-threatening;
- diarrhoea, vomiting or nausea (feeling sick).

Other side effects include:

Very common: (may affect more than 1 in 10 people)
- constipation
- pain in your belly
- infections of the nose, sinuses and throat
- infection of the lungs
- feeling tired or weak
- loss of appetite
- pain that affect different parts of the body - this can range from a sharp pain to a dull ache
- stiff joints
- back pain.

Common: (may affect up to 1 in 10 people)
- an infection of the blood caused by bacteria (sepsis) - this may be due to low levels of white cells in your blood
- flu
- infection of the urinary tract
- hay fever
- anxiety
- loss of weight.

Not known (frequency cannot be estimated from the available data)
- Serious immune reaction (differentiation syndrome) that may cause fever, cough, difficulty breathing, rash, decreased urine, low blood pressure (hypotension), swelling of the arms or legs and rapid weight gain.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product name]

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 carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 [Product name] contains

- The active substance is azacitidine. Each film-coated tablet contains 200 mg or 300 mg azacitidine.
- The other ingredients are croscarmellose sodium (E468), magnesium stearate, mannitol (E421) and cellulose microcrystalline (E460(i)), silica colloidal anhydrous (E551).
- The 200 mg tablet coating – Opadry II green contains: hypromellose (E464), titanium dioxide (E171), lactose monohydrate, macrogol (E1521), triacetin (E1518), iron oxide yellow (E172), indigo carmine (E132) and sunset yellow FCF (E 110).
- The 300 mg tablet coating – Opadry II white contains: hypromellose (E464), titanium dioxide (E171), lactose monohydrate, macrogol (E1521) and triacetin (E1518).

What [Product name] looks like and contents of the pack

[Product name] 200 mg film-coated tablets are light green to green, oval (approximatively 14.7 mm in length and 6.7 mm in width) film-coated tablets, debossed with “TEVA” on one side and “9247” on the other side.

[Product name] 300 mg film-coated tablets are white to off white, oval (approximatively 16.2 mm in length and 8.2 mm in width) film-coated tablets, debossed with “TEVA” on one side and “9248” on the other side.

The film-coated tablets are packaged in blisters consisting of OPA/ALU/PVC//Alu containing 7 or 14 film-coated tablets or unit-dose blisters consisting of OPA/ALU/PVC//Alu containing 7x1 or 14x1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
TEVA GmbH
Graf-Arco-Str. 3
89079 Ulm
Duitsland

Manufacturer
Balkanpharma-Dupnitsa AD
3 Samokovsko Shosse Str.
2600 Dupnitsa
Bulgarije

Teva Czech Industries s.r.o.
Ostravská 29, č.p. 305
747 70 Opava-Komárov
Tsjechië

In het register ingeschreven onder

RVG 135751, filmomhulde tabletten 200 mg
RVG 135753, filmomhulde tabletten 300 mg

This medicine is authorised in the Member States of the European Economic Area under the following names:

België	Azacitidine Teva 200 mg filmomhulde tabletten / comprimés pelliculés / Filmtabletten
	Azacitidine Teva 300 mg filmomhulde tabletten / comprimés pelliculés / Filmtabletten
Duitsland	Azacitidin-ratiopharm 200 mg Filmtabletten
	Azacitidin-ratiopharm 300 mg Filmtabletten
Frankrijk	AZACITIDINE TEVA 200mg, comprimé pelliculé
	AZACITIDINE TEVA 300mg, comprimé pelliculé
Ierland	Azacitidine Teva 200 mg Tablets
	Azacitidine Teva 300 mg Tablets
Italië	Azacitidina Teva
Kroatië	Azacitidin Teva 200 mg filmom obložene tablete
	Azacitidin Teva 300 mg filmom obložene tablete
Luxemburg	Azacitidine Teva 200 mg comprimés pelliculés
	Azacitidine Teva 300 mg comprimés pelliculés
Nederland	Azacitidine Teva 200 mg, filmomhulde tabletten
	Azacitidine Teva 300 mg, filmomhulde tabletten
Oostenrijk	Azacitidin TEVA 200 mg Filmtabletten
	Azacitidin TEVA 300 mg Filmtabletten
Roemenië	Azacitidină Teva 200 mg comprimate filmate
	Azacitidină Teva 300 mg comprimate filmate
Slovenië	Azacitidin Teva 200 mg filmsko obložene tablete
	Azacitidin Teva 300 mg filmsko obložene tablete
Spanje	Azacitidina Teva 200 mg comprimidos recubiertos con película EFG
	Azacitidina Teva 300 mg comprimidos recubiertos con película EFG

Deze bijsluiter is voor het laatst goedgekeurd in november 2026.

Other sources of information

<Latest approved information on this medicine is available by scanning the QR code included in the package leaflet and outer carton with a smartphone/device. The same information is also available on the following URL: [URL to be included] <and the <NCA> website>>

In case that only the URL is mentioned in the PI and not linked via mobile technology, please include:
<Latest approved information on this product is available on the following URL: [URL to be included] <and the <NCA> website>>