



Read all of this leaflet carefully before you start using 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 or pharmacist.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.



## Dacarbazine Injection USP 200mg

### What is in this leaflet

1. What Dacarbazine TAJ PHARMA is and what it is used for
2. What you need to know before you are given Dacarbazine TAJ PHARMA
3. How to use Dacarbazine TAJ PHARMA
4. Possible side effects
5. How to store Dacarbazine TAJ PHARMA
6. Contents of the pack and other information

#### 1. What Dacarbazine TAJ PHARMA is and what it is used for

Dacarbazine belongs to the group of medicines known as cytostatic agents. These agents influence the growth of cancer cells.

Dacarbazine TAJ PHARMA has been prescribed by your doctor for the treatment of cancer, such as:

- advanced malignant melanoma (skin cancer),
- Hodgkin's disease (cancer of the lymphatic tissue),

- soft tissue sarcoma (cancer of muscles, fat, fibrous tissue, blood vessels or other supporting tissue of the body).

Dacarbazine TAJ PHARMA can be used in combination with other cytostatic agents.

#### 2. What you need to know before you are given Dacarbazine TAJ PHARMA

You will not be given Dacarbazine TAJ PHARMA

- if you are allergic to dacarbazine or any of the other ingredients of this medicine (listed in section 6),

- if the number of white blood cells and/or platelets in your blood is too low (leukopenia and/or thrombocytopenia),

- if you have a severe liver or kidney disease,
- if you are pregnant or breastfeeding.

Warnings and precautions

Talk to your doctor or pharmacist before you are given Dacarbazine TAJ PHARMA.

Before each administration you will have blood tests to check that you have enough blood cells to receive this medicine. Your liver and kidney function will also be monitored.

You should not have a live vaccine if you are having Dacarbazine TAJ PHARMA. This is because Dacarbazine TAJ PHARMA may weaken your immune system and make you more likely to catch a serious infection. You should not use fitemustine if you are being treated with Dacarbazine TAJ PHARMA.

Other medicines and Dacarbazine TAJ PHARMA  
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is not advisable to use any medical treatment without telling your doctor as there may be interactions between Dacarbazine TAJ PHARMA and other medicines.

In particular, tell your doctor or pharmacist if you are using or are being treated with any of the following:

- Radiation treatment or other medicines to reduce tumour growth (chemotherapy). Using these medicines with Dacarbazine TAJ PHARMA can increase the damage to your bone marrow.
- Other medicines that are metabolised by a system of liver enzymes called cytochrome P450.
- Methoxyisoralen (for skin problems such as psoriasis and eczema) – Having Dacarbazine TAJ PHARMA with methoxyisoralen can make you more sensitive to sunlight (photosensitisation).
- Phenytoin (used to treat seizures) – Using Dacarbazine TAJ PHARMA and phenytoin at the same time may make it more likely for you to have fits (convulsions).
- Cyclosporine or tacrolimus (used to lower the body's immune reactions) – These medicines may weaken your immune system.
- Fitemustine (used for treatment of skin cancer) – Using Dacarbazine TAJ PHARMA and fitemustine at the same time may lead to damage to your lungs.
- Medicines that can cause liver damage e.g. diazepam (used to treat anxiety, muscle spasms and convulsions), imipramine (used to treat symptoms of depression), ketoconazole (used to treat fungal infections), carbamazepine (used to prevent fits, modify some types of pain or to control mood disorders) should be avoided during chemotherapy.
- Anticoagulants (medicines used to prevent formation of blood clots) – Your doctor will decide whether these medicines will be given to you and will check the clotting tendency of your blood. You should not have a live vaccine if you are having Dacarbazine TAJ PHARMA and during 3 months following completion of treatment with Dacarbazine TAJ PHARMA. This is because Dacarbazine TAJ

PHARMA may weaken your immune system and make you more likely to catch a serious infection. You may have a 'killed' or inactivated vaccine if you are having Dacarbazine TAJ PHARMA.

Dacarbazine TAJ PHARMA with food, drink and alcohol

During chemotherapy you should not drink alcohol.

Pregnancy, breastfeeding and fertility  
Dacarbazine TAJ PHARMA must not be given if you are pregnant, think you may be pregnant or are planning to have a baby.

Do not breastfeed while you are being treated with Dacarbazine TAJ PHARMA.

You must use an effective method of contraception during treatment with Dacarbazine TAJ PHARMA. Men should continue to use effective contraception for at least 6 months after treatment with Dacarbazine TAJ PHARMA has stopped.

If you are thinking of becoming pregnant or of breastfeeding, discuss it with your doctor first.

Driving and using machines  
Your ability to drive or operate machines may be influenced because of central nervous side effects (effects on the brain and nerves) or feeling sick and being sick; but there is no reason why you cannot drive or use machines between courses of therapy with this medicine unless you feel dizzy or unsure of yourself.

3. How to use Dacarbazine TAJ PHARMA

This medicine will be given to you under the direction of a doctor specialised in oncology (cancer treatment) or haematology (the study of diseases of the blood). You will be monitored regularly, during and after your treatment, for any signs of side effects.

Dacarbazine is a substance sensitive to light exposure. The doctor or nurse giving you this medicine will make sure that dacarbazine will be protected from exposure to daylight during administration.

How much Dacarbazine TAJ PHARMA you will be given

Your doctor will calculate the dose you will be given. This will depend on the type of cancer you have and how advanced it is, your body surface area (m<sup>2</sup>), blood counts and other anticancer medicines or treatments you are currently having. The treating physician will also decide individually how long this medicine will be given to you.

Your doctor may change the dose and frequency of dosing depending on your blood test results, your general condition, further therapies and your response to this medicine. If you have any questions about your treatment, ask your doctor, nurse or pharmacist.

Skin cancer (metastatic malignant melanoma)  
The usual dose is 200 – 250 mg per m<sup>2</sup> body surface area, once a day. You are given this dose 5

- Extreme tiredness
- Persistent or severe vomiting or diarrhoea
- Severe allergic reaction – you may experience a sudden itchy rash, swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel like you are going to faint
- Yellowing of the skin and eyes because of liver problems
- Signs of brain-related or nerve-related problems, such as headaches, impaired vision, fits, confusion, lethargy or numbness and tingling of your face
- Severe problems with the liver due to obstruction of the liver blood vessels (veno-occlusive disease [VOD] or Budd-Chiari syndrome) with destruction of liver cells which can be life-threatening. If these complications are suspected, your doctor will decide the right treatment for you.
- These are all serious side effects. You may need urgent medical attention.

The following other side effects may occur:  
Common (may affect up to 1 in 10 people)

- Decreased number of red blood cells (anaemia)
- Decreased number of white blood cells (leukopenia)
- Decreased number of platelets in the blood (thrombocytopenia)

The changes in blood counts are dose-dependent and delayed, with the lowest values often only occurring after 3 to 4 weeks.

- Loss of appetite (anorexia), feeling sick and being sick (all of which may be severe)

Uncommon (may affect up to 1 in 100 people)

- Hair loss (alopecia)
- Increased skin colouring (hyperpigmentation)
- Sensitivity to light (photosensitivity) of the skin
- Flu-like symptoms with exhaustion, chills, fever and muscular pain. These symptoms might happen during administration of the medicine, or a few days after you have been given it. They might also come back the next time you are given dacarbazine.

Rare (may affect up to 1 in 1,000 people)

- Decreased number of all cells in the blood (pancytopenia)
- Severely decreased number of granulocytes, a special type of white blood cells (agranulocytosis)
- Severe allergic (anaphylactic) reaction resulting in e.g. drop in blood pressure, swelling of the hands, feet, ankles, face, lips, mouth and throat which may cause difficulty in swallowing or breathing, rapid pulse, hives and generalised itching or skin redness

- Headaches
- Impaired vision
- Confusion
- Lethargy
- Fits (convulsions)
- Abnormal sensations of the face (facial paraesthesia), numbness and flushing of the face shortly after injection

- Diarrhoea
- Elevation of liver enzymes
- Impaired kidney function
- Red skin (erythema)
- Skin eruptions (maculopapular exanthema)
- Hives (urticaria)
- Application site irritation

If the medicine is accidentally injected into the tissue around your vein, it may be painful and might lead to tissue damage.

You may experience one or several of these symptoms. If you get any side effects, talk to your doctor or pharmacist.

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.

#### 5. How to store Dacarbazine TAJ PHARMA

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

Do not store above 25 °C. Keep the vial in the outer carton in order to protect from light.

The shelf-life under these conditions is 3 years. Freshly prepared (reconstituted) solutions of Dacarbazine TAJ PHARMA were demonstrated to be stable for 24 hours at 20 °C protected from light.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally be no longer than 24 hours at 2 to 8 °C, unless reconstitution has taken place in controlled and validated aseptic conditions. The reconstituted and further diluted solution must be used immediately.

Dacarbazine TAJ PHARMA is for single use only. Any portion of the contents remaining after use should be discarded by your doctor as well as solutions where the visual appearance of the product has changed. The diluted solution for infusion should be visually inspected by your doctor and only clear solutions practically free from particles should be used.

6. Contents of the pack and other information

What Dacarbazine TAJ PHARMA contains

- The active substance is dacarbazine (as dacarbazine citrate).
- The other ingredients are citric acid, anhydrous, and mannitol.

What Dacarbazine TAJ PHARMA looks like and contents of the pack  
Dacarbazine TAJ PHARMA is a white or pale-yellow powder which is supplied in amber glass vials (Type I, Ph.Eur.).

Each single-dose vial of Dacarbazine TAJ PHARMA 200 mg contains 200 mg dacarbazine, as dacarbazine citrate.

After reconstitution Dacarbazine TAJ PHARMA contains 10 mg/ml dacarbazine.

Vials of Dacarbazine TAJ PHARMA are packed in boxes containing 10 vials.

Marketing Authorisation Holder and Manufacturer

Manufactured in India by:  
TAJ PHARMACEUTICALS LTD.

Mumbai, India

at SURVEY NO.188/1 TO 189/1,190/1 TO 4, ATHIYAWAD, DABHEL, DAMAN- 396210 (INDIA)

This leaflet was last revised in May 2019.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria Dacarbazine TAJ PHARMA 100 mg/200 mg, Pulver zur Herstellung einer Injektions-/Infusionslösung

Belgium DACARBAZINE TAJ PHARMA 100 mg/200 mg, poeder voor oplossing voor injectie/infusie

DACARBAZINE TAJ PHARMA 100 mg/200 mg, poudre pour solution injectable/pour perfusion

DACARBAZINE TAJ PHARMA 100 mg/200 mg, Pulver zur Herstellung einer Injektions-/Infusionslösung

Italy Dacarbazine TAJ PHARMA 100 mg/200 mg, polvere per soluzione iniettabile o per infusione

Ireland Dacarbazine TAJ PHARMA 200 mg, powder for solution for injection/infusion

Netherlands Dacarbazine TAJ PHARMA 100 mg/200 mg, poeder voor oplossing voor injectie/infusie

Portugal Dacarbazine TAJ PHARMA 100 mg/200 mg, pó para solução injetável ou para perfusão

Sweden Dacarbazine TAJ PHARMA 100 mg/200 mg, Pulver till injektions-/infusionsvätska, lösning

United Dacarbazine TAJ PHARMA 100 mg/200 mg, powder for solution for injection/infusion

Kingdom

The following information is intended for medical or healthcare professionals only:  
Recommendations for safe handling  
Dacarbazine is an anti-neoplastic agent and should be handled according to standard procedures for cytostatics that have mutagenic, carcinogenic and teratogenic effects. Before commencing, local cytotoxic guidelines should be referred to.

Dacarbazine should only be opened by trained staff

days in a row, every 3 weeks. It will be given as a fast injection into your vein or as a slow infusion into your vein lasting 15 – 30 minutes.

Alternatively, you can be given one larger dose of 850 mg per m<sup>2</sup> body surface area, every 3 weeks.

This will be given as a slow infusion into your vein. Cancer of the lymphatic tissue (Hodgkin's disease)

The usual dose is 375 mg per m<sup>2</sup> body surface area, every 15 days. You will also be given medicines called doxorubicin, bleomycin and vinblastine (this combination is called the ABVD regimen). It will be given as a slow infusion into the vein.

Cancer of muscles, fat, fibrous tissue, blood vessels or other supporting tissue of the body (soft tissue sarcoma)

The usual dose is 250 mg per m<sup>2</sup> body surface area, once a day. You are given this dose 5 days in a row, every 3 weeks. It will be given as a slow infusion into the vein lasting 15 – 30 minutes.

You will also be given a medicine called doxorubicin (this combination is called the ADIC regimen).

Patients with kidney or liver problems  
If you have either mild or moderate kidney or liver problems, you do not usually need to have less of this medicine. If you have both kidney and liver problems, your body will take longer to use the medicine and remove it from your system. Your doctor may give you less of this medicine.

Use in children  
No special recommendations for the use of this medicine in children can be given to your doctor until further data become available.

If you have been given more Dacarbazine TAJ PHARMA than you should  
If you have been given too much Dacarbazine TAJ PHARMA, this may cause a severe decline in your blood cells. It may lead to a complete loss of function of your bone marrow. Possible symptoms include signs of infections, bruising due to an increased bleeding tendency or fatigue. This can be delayed by up to 2 weeks.

If you think you have been given too much Dacarbazine TAJ PHARMA, tell your doctor or nurse straight away. The number of blood cells will be checked and supportive measures such as transfusions may be required.

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

4. Possible side effects  
Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment.

Tell your doctor immediately, if you notice anything of the following:

- Signs of infection, such as sore throat and high temperature
- Abnormal bruising or bleeding

and as with all cytotoxic agents precautions should be taken to avoid exposing staff. Handling of cytotoxic medicinal products should be generally avoided during pregnancy. Preparation of solution for administration should be carried out in a designated handling area and working over a washable tray or disposable plastic-backed absorbent paper.

Suitable eye protection, disposable gloves, face mask and disposable apron should be worn. Syringes and infusion sets should be assembled carefully to avoid leakage (use of Luer lock fittings is recommended).

On completion, any exposed surface should be thoroughly cleaned and hands and face washed. In the event of spillage, operators should put on gloves, face masks, eye-protection and disposable apron and mop up the spilled material with an absorbent material taped in the area for that purpose. The area should then be cleaned and all contaminated material transferred to a cytotoxic spillage bag or bin or sealed for incineration.

Preparation for intravenous administration  
Dacarbazine solutions are prepared immediately before use.

Dacarbazine is sensitive to light exposure. During administration, the infusion container and administration set should be protected from exposure to daylight, e.g. by using light-resistant PVC-infusion sets. Normal infusion sets should be wrapped up in e.g. UV-resistant foils.

Preparation of Dacarbazine TAJ PHARMA 200 mg: Aseptically transfer 20 ml of water for injections into the vial and shake until a solution is obtained. This freshly prepared solution, containing 10 mg/ml of dacarbazine, (density of the solution: = 1.007 g/ml) is administered as a slow injection.

For preparation of Dacarbazine TAJ PHARMA 200 mg for i.v. infusion the freshly prepared solution is further diluted with 200 – 300 ml 0.9 % sodium chloride or 5 % glucose infusion solution. This solution is given as a short term infusion over a period between 15 – 30 minutes.

Dacarbazine TAJ PHARMA 200 mg is for single use only.

The diluted solution for infusion should be visually inspected and only clear solutions practically free from particles should be used. Do not use the solution if particles are present.

Any portion of the contents remaining after use should be discarded, as well as solutions where the visual appearance of the product has changed. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.