Diazepam tablets are used to treat a number of conditions, including:

1. **In adults**:
   - **Short term relief (2-4 weeks) only of severe anxiety, which is an emotional state where you may sweat, tremble, feel anxious and have a fast heart rate and may occur alone or with insomnia (sleeping problems) or mental health problems**
   - **Helping muscles relax and for muscle spasm**
   - **Helping to relax nervous dental patients**
   - **For surgery (especially when given before or with anaesthetics)**
   - **Helping to relax muscle spasm caused by tetanus (when taken with other medicines)**
   - **Helping to relax muscle spasm caused by epilepsy (with or without medicines)**
   - **In children**
   - **In children with learning disabilities**
   - **In children taking sedatives**
   - **In children with epilepsy**
   - **In children with alcohol or sedative dependence (a need to keep taking the medicine over a long period of time)**

2. **How to take Diazepam tablets**

   - **Do not take Diazepam tablets and tell your doctor if you:**
     - **Are allergic (hypersensitive) to diazepam or to any of the other ingredients in your tablets (see section 6)**
     - **Have a phobia (fear of a particular object or situation) or other mental illness**
     - **Have myasthenia gravis (a condition which causes muscles to weaken and tire easily)**
     - **Have haemophilia (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders)**
     - **Are pregnant**

   - **Warnings and precautions**

     - **Talk to your doctor or pharmacist before taking Diazepam tablets** if you:
       - **Have a history of alcoholism or drug abuse**
       - **Have problems with your heart and lungs or have severe kidney failure**
       - **Have someone close to you that has recently died**
       - **Have low blood levels of a protein called albumin**
       - **Have a personality disorder**
       - **Have a poor blood supply to the brain (arterio sclerosis)**
       - **Make you very sleepy**
       - **Barbiturates such as phenobarbital (to treat epilepsy and mental disorders)**
       - **Medicines to lower high blood pressure**
       - **Diuretics (water tablets), nitrates (for heart conditions) as these could lower your blood pressure too much**
       - **Antacids (reduces stomach acid) may slow down absorption of diazepam in the body**
       - **Diazepam can interact with other medicines to lower the blood pressure too much**
       - **If you have any side effects, talk to your doctor or pharmacist**

   - **General anaesthetics and sedatives** (used to treat tuberculosis), as it may increase the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Diazepam tablets together with opioids the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all opioid medicines you are taking, and follow your doctor’s dose recommendation closely. It could be helpful to inform family or relatives to be aware of the signs and symptoms stated above. Contact your doctor if you have an opioid addiction or are experiencing such symptoms.

   - **Diazepam tablets with food and drink**

     - **Do not drink alcohol while you are taking Diazepam tablets. Alcohol may increase the sedative effects of Diazepam tablets and make you very sleepy**
     - **Grapefruit juice may increase the amount of diazepam in your blood**
     - **If you are elderly, suffer from cirrhosis or any of the conditions listed in section 2, this could possibly increase the sedative effects of Diazepam tablets and it is advisable to speak to your doctor or pharmacist.**

   - **Drinks containing caffeine may reduce the effects of Diazepam**

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**Diazepam All Strengths Tablets PIL - UK**

**Item number**: BBBA2207

**Originator**: T. Hull

**Revision Date**: 05/06/18

**Supplier**: Actavis UK

**Date sent**: n/a

**Date received**: n/a

**Pharmacode**: 148x210 (Reel Fed) - Leaflet for Blisters

**Date received**: 13/06/18

**Technologist**: R. Wrey

**Technically Approved**
Pregnancy, breast-feeding and fertility
Do not take Diazepam tablets if you are pregnant, might become pregnant or breast-feeding. If you and your doctor decide that you should take this medicine during the end of your pregnancy (or during labour) this may harm your baby. The baby may have a low temperature, be listless, have breathing problems or difficulty in feeding. Also, if you take this medicine regularly during your pregnancy your baby may get withdrawal symptoms. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Diazepam tablets can make you sleepy, forgetful, have poor co-ordination along with other side-effects that can affect everyday activities (see Possible side-effects). You should not drive, operate machinery or take part in such activities where, if affected, you could put yourself or others at risk.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- You would not be committing an offence if
  - the medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Diazepam tablets contain lactose
Diazepam tablets contain lactose (a type of sugar). If you have been told that you have intolerance to some sugars contact your doctor before taking this medicine.

3. How to take Diazepam tablets
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. You should not take Diazepam tablets for longer than 6 weeks.

Swallow the tablets whole, with a glass of water.

The recommended dose is:

- Adults
  - Anxiety or mental health problems: 5mg-30mg each day, in divided doses.
  - To help you sleep: 5mg-15mg at bedtime.
  - To help control muscle spasms: 5mg-15mg each day, in divided doses.
  - To help with alcohol withdrawal symptoms: 5mg-20mg, which may be repeated after 2 to 4 hours if necessary.
  - Before dental treatment: 5mg the night before treatment, 5mg on waking and 5mg 2 hours before the appointment.
- Before an operation: 5mg-20mg

Use in children
For tension and irritability in cerebral spasticity: 5mg-40mg each day, in divided doses.

If your doctor has given your child Diazepam tablets to take before an operation, the usual dose is 2mg-10mg.

Elderly or Frail
If you are elderly or frail you are likely to be more sensitive to the effects of Diazepam tablets, such as confusion, and your doctor will give you much lower doses. The dose should not be more than half the adult dose.

Kidney or liver impairment
If you have liver or kidney problems you may also be given a lower dose.

If you take more Diazepam tablets than you should If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include clumsiness and loss of coordination, feeling sleepy or deep sleep, speech problems, irregular or slow heartbeat, uncontrolled eye movement, muscle weakness or excitement. An extreme overdose may lead to coma (unrousable unconsciousness), reflex problems and breathing difficulties.

If you forget to take Diazepam tablets
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

Stopping Diazepam tablets and Withdrawal Effects
This medicine should not be stopped suddenly; keep taking it until your doctor tells you how to reduce the dose slowly. If you stop taking the tablets suddenly you may experience the following withdrawal effects:

- depression
- nervousness
- difficulty in sleeping
- irritability
- swelling
- upset stomach/diarrhoea
- your symptoms are being treated for can come back worse than before.
- You may also experience mood changes, anxiety, restlessness and changes in sleep patterns. These effects may occur even after taking low doses for a short period of time. If you stop taking these tablets suddenly after being treated with high doses of Diazepam tablets, you may experience confusion, hallucinations, shaking, faster heartbeat or fits. Withdrawal may also cause unusual behaviour including aggressive outbursts, excitement or depression with suicidal thoughts or actions.
- 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.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed.

Some side effects can be serious and may require immediate medical treatment:

- Uncommon (may affect up to 1 in 100 people)
  - Respiratory depression (very slow and/or shallow breathing)
  - Respiratory arrest (cessation of breathing)
  - Unconsciousness
  - Jaundice (yellowing of your skin or the white of your eye)
  - Very rare (may affect up to 1 in 10,000 people)
  - Sleep problems
  - Anaphylaxis (severe allergic reaction) with symptoms such as sudden wheezing, swelling of your lips, tongue and throat or body rash, fainting or difficulties to swallow
  - Very rarely (may affect up to 1 in 10,000 people)
  - Nausea, vomiting, constipation, diarrhoea
  - Balancing disorders
  -皮下出血

Other side effects:

- Very common (may affect more than 1 in 100 people)
  - Drowsiness
  - Common (may affect up to 1 in 10 people)
  - Confusion
  - Dizziness
  - Loss of co-ordination of muscle movements (ataxia) and other movement disorders, tremor

- Muscle weakness
- Memory loss
- Difficulty in concentrating
- Balance disorders
- Dizziness
- Headache
- Stressed
- Sleep problems
- Stomach and intestinal problems such as nausea, vomiting, constipation, diarrhoea
- Increased salivation
- Allergic skin reactions in the form of itching, skin redness and swelling and skin rash.

Rare (may affect up to 1 in 1,000 people)
Mental side effects such as excitation, agitation, restlessness, irritability, aggressiveness, memory loss, inappropriate behaviour, delusion, rages, psychoses, nightmares or hallucinations. May or may become serious. These side effects are more likely to occur in children or the elderly. Talk to your doctor.

- Decreased alertness
- Depression
- Emotional withdrawal
- Insomnia (problems sleeping)
- Heart problems such as slow heartbeat (bradycardia), heart failure and cessation of heartbeat (cardiac arrest)
- Low blood pressure, fainting (syncope)
- Increased mucus in the lungs
- Dry mouth
- Loss appetite
- Changes in certain liver enzymes as seen in blood tests
- Lack of ability to urinate, loss of bladder control (leakage of urine)
- Breast enlargement in men
- Impotence, changes in sexual drive (libido)
- Changes in certain liver enzymes as seen in blood tests
- Not known (frequency cannot be estimated from the available data)
  - Blurred vision, double vision and involuntary eye movements (these side effects disappear after you have stopped taking Diazepam tablets)

Withdrawal symptoms: see Section 3, ‘If you stop taking Diazepam tablets.’

5. 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Medwatch in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diazepam tablets
Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the label/carrier/bottle. 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 to protect the environment.

6. Contents of the pack and other information
What Diazepam tablets contain

- The active substance (the ingredient that makes the tablet work) is diazepam. Each tablet contains either 2mg, 5mg or 10mg of the active ingredient.
- The other ingredients are lactose, magnesium stearate, maize starch and talc.
- The 5mg tablets also contain quinoline yellow E104.
- The 10mg tablets also contain HI Lake E132.

What Diazepam tablets looks like and contents of the pack
Diazepam tablets are uncoated tablets in the following colours: 2mg-white, 5mg-yellow, 10mg-blue.

Pack sizes are 28 tablets.

Marketing Authorisation Holder and manufacturer
Actavis, Barnstaple, EX32 8NS, UK.

Date of Revision: October 2018

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Diazepam Tablets
All Strengths x 28’s (UK)

Dimensions: 148x210 (Reel Fed)
Component: Leaflet for Blister packs
Pharmacoed: 1102

Date Sent: 13/06/18
Technologist: R.Wrey

Accord BST - Packing Technical
B3CT.CutterGuideReq@accord-healthcare.com