Package leaflet: Information for the patient

Tramadol Hydrochloride Medreich 50 mg, 100 mg, 150 mg and 200 mg Prolonged-release capsules

Tramadol hydrochloride

This medicine contains tramadol hydrochloride which is an opioid, which can cause addiction.
You can get withdrawal symptoms if you stop taking it suddenly.

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet (Section 4).

What is in this leaflet:

1. What Tramadol Hydrochloride Medreich Prolonged-release capsules are and what they are used for
2. What you need to know before you take Tramadol Hydrochloride Medreich Prolonged-release capsules
3. How to take Tramadol Hydrochloride Medreich Prolonged-release capsules
4. Possible Side effects
5. How to store Tramadol Hydrochloride Medreich Prolonged-release capsules
6. Contents of the pack and other information

1. What Tramadol Hydrochloride Medreich Prolonged-release capsules are and what they are used for

The full name of your medicine is 'Tramadol hydrochloride Medreich 50 mg, 100 mg, 150 mg or 200 mg Prolonged-release capsules'. It is referred to as 'Tramadol Hydrochloride Medreich prolonged-release capsule in the rest of this leaflet.

This medicine has been prescribed for you for the treatment of moderate to severe pain.

It contains tramadol hydrochloride which belongs to a class of medicines called opioids which are 'pain relievers'.

This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly.

Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take Tramadol Hydrochloride Medreich Prolonged-release capsules

Do not take Tramadol Hydrochloride Medreich Prolonged-release capsules:
- if you are allergic to tramadol or any of the other ingredients of this medicine (listed in section 6);
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions);
- if you are also taking MAO inhibitors (certain medicines used for treatment of depression) or have taken them in the last 14 days before treatment with Tramadol Hydrochloride Medreich Prolonged-release capsules (see "Other medicines and Tramadol Hydrochloride Medreich Prolonged-release capsules");
- if you are an epileptic and your fits are not adequately controlled by treatment;
- as a substitute in drug withdrawal.

Warnings and precautions
Talk to your doctor before taking this medicine if you:
- suffer from consciousness disorders (if you feel that you are going to faint);
- are in a state of shock (cold sweat may be a sign of this);
- suffer from increased pressure in the brain (possibly after a head injury or brain disease);
- have difficulty in breathing;
- have a tendency towards epilepsy or fits because the risk of a fit may increase;
- Suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see "Other medicines and Tramadol Hydrochloride Medreich Prolonged-release capsules");
- suffer from a liver or kidney disease;
- are going to have an operation, or have just had an operation, please tell your doctor that you are taking Tramadol Hydrochloride Medreich Prolonged-release capsules. Tramadol Hydrochloride Medreich Prolonged-release capsules should not be taken for short-term pain relief after surgery because it may increase the risk of dependence and breathing problems.

Tolerance, dependence, and addiction

This medicine contains tramadol which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Tramadol Hydrochloride Medreich Prolonged-release capsules can also lead to dependence, abuse and addiction, which may result in life threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Tramadol Hydrochloride Medreich Prolonged-release capsules if:
- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Tramadol Hydrochloride Medreich Prolonged-release capsules, it could be a sign that you have become dependent or addicted:
- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Tramadol Hydrochloride Medreich Prolonged-release capsules).

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Tramadol Hydrochloride Medreich prolonged-release Capsules if:
- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

Sleep-related breathing disorders

Tramadol Hydrochloride Medreich Prolonged-release capsules contains an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, such as sleep apnoea (breathing pauses during sleep) and sleep-related hypoxemia (low level of oxygen in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

There is a small risk that you may experience a so-called serotonin syndrome that can occur after having taken tramadol in combination with certain antidepressants or tramadol alone. Seek medical advice immediately if you have any of the symptoms related to this serious syndrome (see section 4 "Possible side effects").

Epileptic fits have been reported in patients taking tramadol at the recommended dose level. The risk may be increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg).

Tramadol is transformed in the liver by an enzyme. Some people have a variation of this enzyme and this can affect people in different ways. In some people, they may not get enough pain relief but other people are more likely to get serious side effects. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Talk to your doctor if you experience any of the following symptoms while taking Tramadol Hydrochloride Medreich Prolonged-release capsules: Extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels). If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

Other medicines and Tramadol Hydrochloride Medreich Prolonged-release capsules

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

Tramadol Hydrochloride Medreich Prolonged-release capsules should not be taken together with MAO inhibitors (certain medicines for the treatment of depression).

The pain-relieving effect of this medicine may be reduced and the length of time it acts may be shortened, if you take medicines which contain
- carbamazepine (for epileptic fits);
- ondansetron (prevents nausea).

Your doctor will tell you whether you should take Tramadol Hydrochloride Medreich Prolonged-release capsules, and which dose.

The risk of side effects increases, if you are taking:
- other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking Tramadol Hydrochloride Medreich Prolonged-release capsules. You may feel drowsier or feel that you might faint. If this happens tell your doctor.
- concomitant use of Tramadol Hydrochloride Medreich Prolonged-release capsules and tranquillizers, sleeping pills (e.g. benzodiazepines) or other sedatives or medicines that impair breathing activity (e.g. opioids) or gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain) increases 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 prescribes Tramadol Hydrochloride Medreich Prolonged-release capsules together with sedating medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedating medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.
- medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk having a fit may increase if you take Tramadol Hydrochloride Medreich Prolonged-release capsules at the same time. Your doctor will tell you whether Tramadol Hydrochloride Medreich Prolonged-release capsules are suitable for you.
- certain antidepressants Tramadol Hydrochloride Medreich Prolonged-release capsules may interact with these medicines and you may experience serotonin syndrome (see section 4 "Possible side effects").
- coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Tramadol Hydrochloride Medreich Prolonged-release capsules. The effect of these medicines on blood clotting may be affected and bleeding may occur.
- medicines that might have anticholinergic effects, such as:
  - medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics).
  - medicines to treat psychiatric disorders (antipsychotics or neuroleptics).
  - muscle relaxants.
  - medicines to treat Parkinson's disease.

  as they may increase the risk of side effects like constipation, urinary retention, dry mouth or dry eyes.

Tramadol Hydrochloride Medreich Prolonged-release capsules with food and alcohol

Do not drink alcohol during treatment with this medicine as its effect may be intensified.

Food does not influence the effect of Tramadol Hydrochloride Medreich Prolonged-release capsules.

Children and adolescents

Use in children with breathing problems:

Tramadol is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

Pregnancy, breast-feeding and fertility

Do not take Tramadol Hydrochloride Medreich Prolonged-release capsules if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Tramadol Hydrochloride Medreich Prolonged-release capsules during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Tramadol Hydrochloride Medreich

This section is continued overleaf →

16.5 mm
6 mm
16.5 mm
50 mm

Space for PC

Space for Item Code - 123XXXX-V1

Prolonged-release capsules while you are breastfeeding as tramadol passes into breast milk and will affect your baby.
Based on human experience tramadol is suggested not to influence female or male fertility.

Driving and using machines
Tramadol Hydrochloride Medreich Prolonged-release capsules may cause drowsiness, dizziness and blurred vision and therefore may impair your reactions. If you feel that your reactions are affected, do not drive a car or other vehicle, do not use electric tools or operate machinery.

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.
- However, 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.
There is further information for patients who are intending to drive in Great Britain - go to https://www.gov.uk/drug-driving-law.

3. How to take Tramadol Hydrochloride Medreich Prolonged-release capsules

Always take this Tramadol Hydrochloride Medreich Prolonged-release capsules exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Tramadol Hydrochloride Medreich Prolonged-release capsules when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also section 2).
The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity. In general the lowest pain-relieving dose should be taken. Do not take more than 400 mg tramadol hydrochloride daily, except if your doctor has instructed you to do so.
Unless otherwise prescribed by your doctor, the usual dose is:

Adults and adolescents from the age of 12 years
One or two Tramadol Hydrochloride Medreich 50 mg Prolonged-release capsule(s) twice daily (equivalent to 100 mg - 200 mg tramadol hydrochloride per day), preferably in the morning and evening.
One Tramadol Hydrochloride Medreich 100 mg Prolonged-release capsule twice daily (equivalent to 200 mg tramadol hydrochloride per day), preferably in the morning and evening.
One Tramadol Hydrochloride Medreich 150 mg Prolonged-release capsule twice daily (equivalent to 300 mg tramadol hydrochloride per day), preferably in the morning and evening.
One Tramadol Hydrochloride Medreich 200 mg Prolonged-release capsule twice daily (equivalent to 400 mg tramadol hydrochloride per day), preferably in the morning and evening.
Your doctor may prescribe a different, more appropriate dosage strength of tramadol hydrochloride if necessary.
If necessary, the dose may be increased up to 150 mg or 200 mg twice daily (equivalent to 300 mg - 400 mg tramadol hydrochloride per day).

Children
Tramadol Hydrochloride Medreich Prolonged-release capsules are not suitable for children below the age of 12 years.

Elderly patients
In elderly patients (above 75 years) the excretion of tramadol may be delayed. If this applies to you, your doctor may recommend prolonging the dosage interval.

Severe liver or kidney disease (insufficiency)/ dialysis patients
Patients with severe liver and/or kidney insufficiency should not take Tramadol Hydrochloride Medreich Prolonged-release capsules. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

How and when should you take Tramadol Hydrochloride Medreich Prolonged-release capsules?
Tramadol Hydrochloride Medreich Prolonged-release capsules are for oral use.
Always swallow Tramadol Hydrochloride Medreich Prolonged-release capsules whole, not divided or chewed, with sufficient liquid, preferably in the morning and evening. You may take the capsule on an empty stomach or with meals.

How long should you take Tramadol Hydrochloride Medreich Prolonged-release capsules?
Your prescriber should have discussed with you, how long the course of /capsules will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

If you take more Tramadol Hydrochloride Medreich Prolonged-release capsules than you should
If you have taken an additional dose by mistake, this will generally have no negative effects. You should take your next dose as prescribed.
After taking very high doses, pin-point pupils, vomiting, fall in blood pressure, fast heart beat, collapse, disturbed consciousness up to coma (deep unconsciousness), epileptic fits, and difficulty in breathing up to cessation of breathing and death may occur. In such cases a doctor should be called immediately.

If you forget to take Tramadol Hydrochloride Medreich Prolonged-release capsules
If you forget to take the capsule, pain is likely to return. Do not take a double dose to make up for forgotten individual doses, simply continue taking the capsule as before.

If you stop taking Tramadol Hydrochloride Medreich Prolonged-release capsules
Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.
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.

You should see a doctor immediately if you experience symptoms of an allergic reaction such as swollen face, tongue and/or throat, and/or difficulty swallowing or hives together with difficulties in breathing.
The most common side effects during treatment with Tramadol Hydrochloride Medreich Prolonged-release capsules are nausea and dizziness, which occur in more than 1 in 10 people.
Very common (may affect more than 1 in 10 people),
- dizziness
- feeling sick (nausea)

Common (may affect up to 1 in 10 people),
- headaches, drowsiness
- fatigue
- constipation, dry mouth, being sick (vomiting)
- sweating (hyperhidrosis)

Uncommon (may affect up to 1 in 100 people),
- effects on the heart and blood circulation (pounding of the heart, fast heartbeat, feeling faint or collapse). These adverse effects may particularly occur in patients in an upright position or under physical strain.
- urge to be sick (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhea.
- skin reactions (e.g. itching, rash)

Rare (may affect up to 1 in 1,000 people)
- allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin) and shock (sudden circulation failure) have occurred in very rare cases.
- slow heartbeat
- increase in blood pressure
- abnormal sensations (e.g. itching, tingling, numbness), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders.
- epileptic fits have occurred mainly at high doses of tramadol or when tramadol was taken at the same time as other medicines which may induce fits.
- changes in appetite
- hallucination, confusional state, sleep disorders, delirium, anxiety and nightmares
- psychological complaints may appear after treatment with Tramadol Hydrochloride Medreich Prolonged-release capsules. Their intensity and nature may vary (according to the patient's personality and length of therapy). These may appear as a change in mood (mostly high spirits, occasionally irritated mood), changes in activity (usually suppression, occasionally increase) and decreased cognitive and sensory perception (being less aware and less able to make decisions, which may lead to errors in judgment).
- drug dependence may occur.
- blurred vision, excessive dilation of the pupils (mydriasis), constriction of the pupils (miosis)
- slow breathing, shortness of breath (dyspnoea)
- worsening of asthma has been reported, however it has not been established whether it was caused by tramadol. If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.
- weak muscles
- passing urine with difficulty or pain, passing less urine than normal (dysuria).

Very rare (may affect up to 1 in 10,000 people).
- hepatic enzyme increased

Not known: frequency cannot be estimated from the available data
- decrease in blood sugar level
- hiccups
- serotonin syndrome, that can manifest as mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as fever, increase in heart rate, unstable blood pressure, involuntary twitching, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) (see section 2 'What you need to know before you take Tramadol Hydrochloride Medreich Prolonged-release capsule).
- sleep apnoea (breathing pauses during sleep)
- dependence and addiction (see section 'How do I know if I am addicted)

Drug Withdrawal
When you stop taking Tramadol Hydrochloride Medreich Prolonged-release capsules, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?
If you notice any of the following signs whilst taking Tramadol Hydrochloride Medreich Prolonged-release capsules, it could be a sign that you have become addicted.
- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

Reporting of side efects
If you get any side effects talk to your doctor or pharmacist. 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 Yellow Card 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 Tramadol Hydrochloride Medreich Prolonged-release capsules

Keep this medicine out of the sight and reach of children.
Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.
Do not use this medicine after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Tramadol Hydrochloride Medreich Prolonged-release capsules contain
50 mg: Each Prolonged-release capsule contains tramadol hydrochloride 50 mg.
100 mg: Each Prolonged-release capsule contains tramadol hydrochloride 100 mg.
150 mg: Each Prolonged-release capsule contains tramadol hydrochloride 150 mg.
200 mg: Each Prolonged-release capsule contains tramadol hydrochloride 200 mg.

The other ingredients are:
Capsule contents: Hypromellose, Cellulose Microcrystalline, Silica Colloidal Anhydrous, Magnesium Stearate.

50 mg
Capsule Shell: Titanium dioxide (E171), Iron oxide yellow (E172), Patent Blue V (E131), Gelatin, Purified Water
100 mg
Capsule shell: Titanium dioxide (E171), Iron oxide yellow (E172), Gelatin, Purified Water
150 mg
Capsule shell: Titanium dioxide (E171), Iron oxide yellow (E172), Gelatin , Indigotine (E132), Purified Water
200 mg
Capsule shell: Titanium dioxide (E171), Iron oxide yellow (E172), Gelatin, Purified Water
Printing ink:
Shellac, Black Iron Oxide, Potassium Hydroxide, Strong Ammonia Solution, Propylene Glycol, Purified Water

What Tramadol Hydrochloride Medreich Prolonged-release capsules look like and contents of the pack
50 mg: Hard gelatin capsule of size '1' with yellow opaque cap marked '50SR' with black color and yellowish green opaque body containing white to off white tablet debossed with 'T0' on one side and plain on other side.
100 mg: Hard gelatin capsule of size '1' with white opaque cap marked '100SR' with black color and white opaque body containing white to off white tablet debossed with 'T1' on one side and plain on other side.
150 mg: Hard gelatin capsule of size '1' with dark green opaque cap marked '150SR' with black color and dark green opaque body containing white to off white tablet debossed with 'T2' on one side and plain on other side.
200 mg: Hard gelatin capsule of size '1' with yellow cap marked '200SR' with black color and yellow body containing white to off white tablet debossed with 'T3' on one side and plain on other side.
Tramadol Hydrochloride Medreich 50 mg, 100 mg, 150 mg and 200 mg Prolonged release capsules are available in Alu/PVC-PVDC blister pack of 7, 10, 14, 30, 60 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
MEDREICH PLC
Warwick House, Plane Tree Crescent,
Feltham TW13 7HF, United Kingdom
E-mail: info@medreich.co.uk

This leaflet was last revised in 09/2026 **POM**

To request a copy of this leaflet in Braille or large print, please call, 02088311580 (UK only)
Please be ready to give the following information: product name and licence number which can be found on the carton.

Space for Item Code - 123XXXX-V1

Colours:

Red 032 C

Black

Font Type & Size	**Times New Roman**
	Heading - 12 pts
	Body - 9 pts
Version	**V-2**

Unit 7

MEDREICH LIMITED				**Title: Art Work Approval Form**			
Product	**Tramadol Hydrochloride Medreich Capsules - S/L - English - PIL** **SAP Descr.: TRAMADOL HCL MED PR CAPS PIL S/L ENG-WOA**			Specification:	**Printed on 40.5 (±3.5) GSM news print paper**		
Customer	**MEDREICH PLC, UK**						
Reason for Issue	**AWR No.:** **Old Code: 1229843-V1** **a) Updating the PIL in-line with RMP**			Colours:	**2 - Red 032 C & Black**		
Related FG Codes	**1307553 / 1307558 / 1307577 / 1307576**	Pharmacode No.	**XXXX**	Dimensions:	**700 x 140 mm (Open Size) 140 x 39 mm (Folded Size)**		
Item Code	**123XXXX-V1**	Blister Layout No.	NA	No. of Folds (only for PIL)	**05**	Artwork made to	**100%**
		Carton Layout No.	NA				
		PIL Layout No.	NA				
Verified By				Approved By			
PDC:		**PDC:**		**Regulatory:**		**CQA:**	