For the use only of Registered Medical Practitioner

1. Generic Name and Brand Name
Gabapentin Capsules I.P. 300 mg
GABASELIS™ 300

2. Qualitative and Quantitative Composition:
Each hard gelatin capsule contains:
Gabapentin I.P. .....300 mg
Excipients .....q.s.
Approved colours used in empty capsule shells

3. Dosage Form & strength
Refer section 1 & 2

4. Clinical particulars
4.1 Therapeutic indication
It is indicated for Epilepsy.

4.2 Posology and method of administration
Posology
Epilepsy with partial onset seizures.

Patients 12 years of age and above: starting dose of Gabapentin is 300 mg three times a day.
The recommended maintenance dose of Gabapentin is 300 mg to 600 mg three times a day.
Dosages up to 2400 mg/day have been well tolerated in long term clinical studies.

Pediatric patients aged 3 to 11 years: Starting dose range is 10 mg/kg/day to 15 mg/kg/day given in three divided doses, and recommended maintenance dose reached by upward titration over a period of approximately 3 days. Recommended age, dose up to 50 mg/kg/day have been well tolerated in long term clinical study.
Maximum time interval between doses should not exceed 12 hours.

Dosage adjustment for renal impairment or hemodialysis in patients of 12 years & older:
For creatinine clearance < 30 to 59 ml/min, total daily dose is 400 to 1400 mg/day in divided dose.
For creatinine clearance > 15 to 29 ml/min, total daily dose is 200 to 700 mg/day.
For creatinine clearance for 15 ml/min, total daily dose is 100 to 300 mg/day.

Method of Administration:
For oral use.
Gabapentin can be given with or without food and should be swallowed whole with sufficient fluid intake (e.g. a glass of water).

4.3 Contraindications
In patients with history of hypersensitivity to Gabapentin or to any of excipients of this product.

4.4 Special warnings and precautions for use
Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and Drug rash with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported in association with gabapentin treatment. At the time of prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, gabapentin should be withdrawn immediately and an alternative treatment considered (as appropriate).
If the patient has developed a serious reaction such as SJS, TEN or DRESS with the use of gabapentin, treatment with gabapentin must not be restarted in this patient at any time. Gabapentin should not abruptly discontinued because of possibility of increasing seizure frequency as it may precipitate status epilepticus.

Anaphylaxis
Gabapentin can cause anaphylaxis. Signs and symptoms in reported cases have included difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment. Patients should be instructed to discontinue gabapentin and seek immediate medical care should they experience signs or symptoms of anaphylaxis.

Suicidal ideation and behaviour
Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic agents in several indications. A meta-analysis of randomised placebo controlled trials of anti-epileptic drugs has also shown a small increased risk of suicidal ideation and behaviour. The mechanism of this risk is not known. Cases of suicidal ideation and behaviour have been observed in patients treated with gabapentin in the post-marketing experience. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge. Patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Discontinuation of gabapentin treatment should be considered in case of suicidal ideation and behaviour.

Acute pancreatitis
If a patient develops acute pancreatitis under treatment with gabapentin, discontinuation of gabapentin should be considered.

Myasthenia gravis
Gabapentin should be used with caution in patients with myasthenia gravis as post-marketing cases of exacerbation of myasthenia gravis have been reported with gabapentin.

Seizures
Although there is no evidence of rebound seizures with gabapentin, abrupt withdrawal of anticonvulsants in epileptic patients may precipitate status epilepticus.

As with other antiepileptic medicinal products, some patients may experience an increase in seizure frequency or the onset of new types of seizures with gabapentin.

As with other anti-epileptics, attempts to withdraw concomitant anti-epileptics in treatment refractive patients on more than one antiepileptic, in order to reach gabapentin monotherapy have a low success rate.

Gabapentin is not considered effective against primary generalized seizures such as absences and may aggravate these seizures in some patients. Therefore, gabapentin should be used with caution in patients with mixed seizures including absences.

Gabapentin treatment has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall). There have also been post-marketing reports of confusion, loss of consciousness and mental impairment. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medication.

Concomitant use with opioids and other CNS depressants
Patients who require concomitant treatment with central nervous system (CNS) depressants, including opioids, should be carefully observed for signs of CNS depression, such as somnolence, sedation, and respiratory depression. Patients who use gabapentin and morphine concomitantly may experience increases in gabapentin concentrations. The dose of gabapentin, or concomitant treatment with CNS depressants including opioids, should be reduced appropriately.

Caution is advised when prescribing gabapentin concomitantly with opioids due to risk of CNS depression. In a population-based, observational, nested case-control study of opioid users, co-prescription of opioids and gabapentin was associated with an increased risk for opioid-related death compared to opioid prescription use alone (adjusted odds ratio [aOR], 1.49 [95% CI, 1.18 to 1.88, $p<0.001$]).

Respiratory depression
Gabapentin has been associated with severe respiratory depression. Patients with compromised respiratory function, respiratory or neurological disease, renal impairment, concomitant use of CNS depressants and the elderly might be at higher risk of experiencing this severe adverse reaction. Dose adjustments might be necessary in these patients.

Elderly (over 65 years of age)
No systematic studies in patients 65 years or older have been conducted with gabapentin. In one double blind study in patients with neuropathic pain, somnolence, peripheral oedema and asthenia occurred in a somewhat higher percentage in patients aged 65 years or above, than in younger patients. Apart from these findings, clinical investigations in this age group do not indicate an adverse event profile different from that observed in younger patients.

Paediatric population
The effects of long-term (greater than 36 weeks) gabapentin therapy on learning, intelligence, and development in children and adolescents have not been adequately studied. The benefits of prolonged therapy must therefore be weighed against the potential risks of such therapy.

Drug dependence, tolerance and potential for abuse
Gabapentin can cause drug dependence, which may occur at therapeutic doses. Cases of abuse and misuse have been reported. Drug addiction comprises behavioural, cognitive and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use and possible tolerance or physical dependence. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, which manifests as withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug. Addiction and dependence are related but distinct presentations and in discussing these themes, terminology that apportion blame to the individual should be avoided.

For all patients, prolonged use of this product may lead to drug dependence and addiction but can occur with short-term use at recommended therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g., major depression).

Additional support and monitoring may be necessary when prescribing for patients at risk of drug misuse.

A comprehensive patient history should be taken to document concomitant medications, including over-the-counter medicines and medicines obtained on-line, and past and present medical and psychiatric conditions.

Patients may find that treatment is less effective with chronic use and express a need to increase the dose to obtain the same level of symptom control as initially experienced. Patients may also supplement their treatment with additional medications to achieve the same effect. These could be signs that the patient is developing tolerance. The risks of developing tolerance should be explained to the patient.

Overuse or misuse may result in overdose and/or death. It is important that patients only use medicines that are prescribed for them at the dose they have been prescribed and do not give this medicine to anyone else.

Patients should be closely monitored for signs of misuse, abuse, or addiction.

The clinical need for treatment with gabapentin should be reviewed regularly, with frequent assessments of patients being undertaken during the course of their treatment.

Drug withdrawal syndrome and Withdrawal symptoms.

Prior to starting treatment with gabapentin, a discussion should be held with patients to explain the risk of dependence, addiction, and drug withdrawal syndrome. A withdrawal strategy for ending treatment with gabapentin should also be put in place with the patient before starting treatment (there may be exceptions to this in specific clinical situations such as symptom management in end of life palliative care, and for use in epilepsy).

Drug withdrawal syndrome may occur upon abrupt cessation of therapy. When a patient no longer requires therapy, it is advisable to taper the dose gradually to minimise symptoms of withdrawal. Tapering from a high dose may take in excess of weeks or months.

Gabapentin should not be discontinued abruptly.

4.5 Drug Interactions

No interaction between gabapentin and phenobarbital, phenytoin, valproic acid or carbamazepoine has been observed. Co-administration of Gabapentin with Hydrocodone decreases hydrocodone exposure. Co-administration of Gabapentin with morphine may cause signs of CNS depression, such as somnolence, sedation and respiratory depression. Concomitant use of magnesium and aluminum hydroxides antacid with gabapentin reduces gabapentin bioavailability by about 20%.

4.6 Use in special populations (Pregnancy, Nursing woman, Pediatric use, Geriatric use)

Pregnancy:

Risk related to epilepsy and antiepileptic drugs (AEDs) in general

Specialist advice regarding the potential risk to a foetus caused by both seizures and antiepileptic treatment should be given to women of childbearing potential, and especially to women planning for pregnancy and women who are pregnant. The need for antiepileptic treatment should be reviewed when a woman is planning to become pregnant. In women being treated for epilepsy, no sudden discontinuation of antiepileptic therapy should be undertaken as this may lead to breakthrough seizures, which could have serious consequences for both mother and child. Monotherapy should be preferred whenever possible because therapy with multiple AEDs could be associated with a higher risk of congenital malformations than monotherapy, depending on the antiepileptics used.

Risk related to gabapentin

Gabapentin crosses the human placenta.

Data from a Nordic observational study of more than 1700 pregnancies exposed to gabapentin in the first trimester showed no higher risk of major congenital malformations among the children exposed to gabapentin compared to the unexposed children and compared to the children exposed to pregabalin, lamotrigine and pregabalin or lamotrigine. Likewise, no increased risk of neurodevelopmental disorders was observed in children exposed to gabapentin during pregnancy. There was limited evidence of a higher risk of low birth weight and preterm birth but not of stillbirth, small for gestational age, low Apgar score at 5 minutes and microcephaly in newborns of women exposed to gabapentin.

Studies in animals have shown reproductive toxicity. Gabapentin can be used during the first trimester of pregnancy if clinically needed. Neonatal withdrawal syndrome has been reported in newborns exposed in utero to gabapentin. Co-exposure to gabapentin and opioids during pregnancy may increase the risk of neonatal withdrawal syndrome. Newborns should be monitored carefully. If used during pregnancy, gabapentin may lead to withdrawal symptoms in newborn infants. This risk might be increased when gabapentin is taken together with opioid analgesics (drugs for treatment of severe pain).

Lactation: Gabapentin is secreted into human milk causing exposure to nursed infant. Use in woman who are nursing only if benefits clearly outweigh risks.

Paediatric population: The effects of long-term (greater than 36 weeks) gabapentin therapy on learning, intelligence, and development in children and adolescents have not been adequately studied. The benefits of prolonged therapy must therefore be weighed against the potential risks of such therapy.

Elderly (over 65 years of age): No systematic studies in patients 65 years or older have been conducted with gabapentin. In one double blind study in patients with neuropathic pain, somnolence, peripheral oedema and asthenia occurred in a somewhat higher percentage in patients aged 65 years or above, than in younger patients. Apart from these findings, clinical investigations in this age group do not indicate an adverse event profile different from that observed in younger patients.

4.7 Effects on ability to drive and use machines

Like all anticonvulsants, the mode of action of gabapentin is on the central nervous system. Drowsiness, dizziness, or other related symptoms may occur upon administration of gabapentin. These incidents, although mild or moderate, may be dangerous in patients driving or operating machinery, particularly until when the individual patients experience with the drug is established.

4.8 Undesirable effects

The adverse reactions observed during clinical studies conducted in epilepsy (adjunctive and monotherapy) and neuropathic pain have been provided in a single list below by class and frequency [very common (≥ 1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1,000) and very rare (< 1/10,000)]. Where an adverse reaction was seen at different frequencies in clinical studies, it was assigned to the highest frequency reported.

Additional reactions reported from post-marketing experience are included as frequency Not known (cannot be estimated from the available data) in italics in the list below.

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Infections and infestations

Very Common: Viral infection.
Common: Pneumonia, respiratory infection, urinary tract infection, infection, otitis media.

Blood and the lymphatic system disorders
Common: leucopenia.
Not known: thrombocytopenia.

Immune system disorders
Uncommon: allergic reactions (e.g. urticaria).
Not known: hypersensitivity syndrome, (a systemic reaction with a variable presentation that can include fever, rash, hepatitis, lymphadenopathy, eosinophilia, and sometimes other signs and symptoms), anaphylaxis.

Metabolism and Nutrition Disorders
Common: anorexia, increased appetite.
Uncommon: hyperglycaemia (most often observed in patients with diabetes).
Rare: hypoglycaemia (most often observed in patients with diabetes).
Not known: hyponatremia.

Psychiatric disorders
Common: hostility, confusion and emotional lability, depression, anxiety, nervousness, thinking abnormal.
Uncommon: agitation.
Not known: suicidal ideation, hallucinations, drug dependence.

Nervous system disorders
Very Common: somnolence, dizziness, ataxia.
Common: convulsions, hyperkinesias, dysarthria, amnesia, tremors, insomnia, headache, sensations such as paresthesia, hypaesthesia, coordination abnormal, nystagmus, increased, decreased, or absent reflexes.
Uncommon: hypokinesia, mental impairment.
Rare: Loss of consciousness.
Not known: other movement disorders (e.g. choreoathetosis, dyskinesia, dystonia).

Eye disorders
Common: visual disturbances such as amblyopia, diplopia.

Ear and Labyrinth disorders
Common: vertigo.
Not known: tinnitus.

Cardiac disorders
Uncommon: palpitations.

Vascular disorder
Common: hypertension, vasodilatation.

Respiratory, thoracic and mediastinal disorders
Common: dyspnoea, bronchitis, pharyngitis, cough, rhinitis.
Rare: respiratory depression.

Gastrointestinal disorders
Common: vomiting, nausea, dental abnormalities, gingivitis, diarrhea, abdominal pain, dyspepsia, constipation, dry mouth or throat, flatulence.
Uncommon: dysphagia.
Not known: pancreatitis.

Hepatobiliary disorders
Not known: hepatitis, jaundice.

Skin and subcutaneous tissue disorders
Common: facial oedema, purpura most often described as bruises resulting from physical trauma, rash, pruritus, acne.
Not known: Stevens-Johnson syndrome, toxic epidermal necrolysis, angioedema, erythema multiforme, alopecia, drug rash with eosinophilia and systemic symptoms.

Musculoskeletal and connective tissue disorders
Common: arthralgia, myalgia, back pain, twitching.
Not known: rhabdomyolysis, myoclonus, Exacerbation of myasthenia gravis, myoclonus.

Renal and urinary disorders
Not known: acute renal failure, incontinence.

Reproductive system and breast disorders
Common: impotence.
Not known: breast hypertrophy, gynaecomastia, sexual dysfunction (including changes in libido, ejaculation disorders and anorgasmia).

General disorders and administration site conditions
Very Common: fatigue, fever.
Common: peripheral oedema, abnormal gait, asthenia, pain, malaise, flu syndrome
Uncommon: generalized oedema.
Not known: withdrawal reactions*, chest pain. Sudden unexplained deaths have been reported where a causal relationship to treatment with gabapentin has not been established.

Investigations
Common: WBC (white blood cell count) decreased, weight gain.
Uncommon: elevated liver function tests SGOT (AST), SGPT (ALT) and bilirubin
Not known: blood creatine phosphokinase increased.

Injury, poisoning and procedural complications
Common: accidental injury, fracture, abrasion.
Uncommon: fall.

*After discontinuation or dose reduction of short-term and long-term treatment with gabapentin, withdrawal symptoms have been observed. Withdrawal symptoms may occur shortly after discontinuation or dose reduction, usually within 48 hours. Most frequently reported symptoms include anxiety, diarrhoea, flu syndrome, convulsions, nervousness, depression, suicidal ideation, hyperhidrosis and insomnia, nausea, pains, sweating, tremor, headache, depression, feeling abnormal, dizziness, and malaise. These symptoms may indicate drug dependence. The occurrence of withdrawal symptoms following discontinuation of gabapentin may indicate drug dependence. The patient should be informed about this at the start of the treatment. Concerning discontinuation of long-term treatment of gabapentin, data suggest that the incidence and severity of withdrawal symptoms may be dose-related. If gabapentin should be discontinued, it is recommended this should be done gradually over a minimum of 1 week independent of the indication.

Under treatment with gabapentin, cases of acute pancreatitis were reported. Causality with gabapentin is unclear.

In patients on haemodialysis due to end-stage renal failure, myopathy with elevated creatine kinase levels has been reported.

Respiratory tract infections, otitis media, convulsions and bronchitis were reported only in clinical studies in children. Additionally, in clinical studies in children, aggressive behaviour and hyperkinesias were reported commonly**.**

4.9 Overdose
Symptoms: Double vision, slurred speech, drowsiness, lethargy, coma and diarrhea.
Treatment: Supponive care is recommended. Gabapentin can be removed by hemodialysis & may be indicated by patient's clinical state or in patients with significant renal impairment.

5. Pharmacological properties

5.1 Mechanism of action

Gabapentin readily enters the brain and prevents seizures in a number of animal models of epilepsy. Gabapentin does not possess affinity for either GABAA or GABAB receptor nor does it alter the metabolism of GABA. It does not bind to other neurotransmitter receptors of the brain and does not interact with sodium channels. Gabapentin binds with high affinity to the α2δ (alpha-2-delta) subunit of voltage-gated calcium channels and it is proposed that binding to the α2δ subunit may be involved in gabapentin's antiseizure effects in animals. Broad panel screening does not suggest any other drug targets other than α2δ.

Evidence from several preclinical models inform that the pharmacological activity of gabapentin may be mediated via binding to α2δ through a reduction in release of excitatory neurotransmitters in regions of the central nervous system. Such activity may underlie gabapentin's anti-seizure

activity. The relevance of these actions of gabapentin to the anticonvulsant effects in humans remains to be established.

Gabapentin also displays efficacy in several preclinical animal pain models. Specific binding of gabapentin to the α2δ subunit is proposed to result in several different actions that may be responsible for analgesic activity in animal models. The analgesic activities of gabapentin may occur in the spinal cord as well as at higher brain centers through interactions with descending pain inhibitory pathways. The relevance of these preclinical properties to clinical action in humans is unknown.

5.2 Pharmacodynamic Properties

Gabapentin is an anticonvulsant structurally related to the neurotransmitter gamma-aminobutyric acid (GABA) but its mechanism of action is different from that of several drugs that interact with GABA synapses.

The identification and function of the gabapentin binding site remains to be elucidated and the significance of its various actions to the anticonvulsant effect remains to be established.
Analgesic activity has been shown in animal models of inflammatory and neuropathic pain.

5.3 Pharmacokinetic properties

Absorption

Gabapentin bioavailability (fraction of dose absorbed) tends to decrease with increasing dose. Absolute bioavailability of a 300 mg capsule is approximately 60%.
Food, including a high-fat diet, has no clinically significant effect on gabapentin pharmacokinetics. Gabapentin pharmacokinetics are not affected by repeated administration. Although plasma gabapentin concentrations were generally between 2 μg/ml and 20 μg/ml in clinical studies, such concentrations were not predictive of safety or efficacy.

Distribution

Gabapentin is not bound to plasma proteins and has a volume of distribution equal to 57.7 litres. In patients with epilepsy, gabapentin concentrations in cerebrospinal fluid (CSF) are approximately 20% of corresponding steady-state trough plasma concentrations. Gabapentin is present in the breast milk of breast-feeding women.

Biotransformation

There is no evidence of gabapentin metabolism in humans. Gabapentin does not induce hepatic mixed function oxidase enzymes responsible for drug metabolism.

Elimination

Gabapentin is eliminated unchanged solely by renal excretion. The elimination half-life of gabapentin is independent of dose and averages 5 to 7 hours.
In elderly patients, and in patients with impaired renal function, gabapentin plasma clearance is reduced. Gabapentin elimination-rate constant, plasma clearance, and renal clearance are directly proportional to creatinine clearance.

Gabapentin is removed from plasma by haemodialysis. Dosage adjustment in patients with compromised renal function or undergoing haemodialysis is recommended.
Gabapentin pharmacokinetics in children were determined in 50 healthy subjects between the ages of 1 month and 12 years. In general, plasma gabapentin concentrations in children > 5 years of age are similar to those in adults when dosed on a mg/kg basis.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Acute Toxicity: Gabapentin exhibited a very low order of acute toxicity in rodents and monkeys. In adult and 3 week old mice, no deaths occurred and median lethal doses (MLD's) were not identified, being greater than 8000, 2000, and 4000 mg/kg by the oral, intravenous, and subcutaneous routes, respectively. In adult and 3 week old rats, MLD's after single oral and intravenous doses were greater than 8000 and 2000 mg/kg, respectively. No signs of toxicity were noted in monkeys given single oral doses of gabapentin up to 1250 mg/kg.

Chronic Toxicity: Multidose oral administration of gabapentin was well tolerated in all species tested (mice, rats, dogs, monkeys). Decreased body weight gain was observed in rats; hypoactivity, emesis, and salivation were observed in dogs; and changes in fecal consistency were noted in all species except mice. Increased kidney weights in male rats correlated with the accumulation of hyaline droplets in renal proximal tubular epithelium. No changes were found in the kidneys of female rats.

7. Description

Size "1" Hard gelatin capsule having Red coloured cap and White coloured body containing white coloured granular powder.

8. Pharmaceutical particulars

8.1 Incompatibilities

Not applicable

8.2 Shelf Life

Refer Pack

8.3 Packaging Information

Refer Pack

8.4 Storage condition

Store protected from moisture, at a temperature not exceeding 30°C.

9. Patient Counseling Information

Administration Information

Inform patients that Gabapentin is taken orally with or without food. Inform patients that, should they divide the scored 600 mg or 800 mg tablet in order to administer a half-tablet, they should take the unused half-tablet as the next dose. Advise patients to discard half-tablets not used within 28 days of dividing the scored tablet.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity

Prior to initiation of treatment with Gabapentin, instruct patients that a rash or other signs or symptoms of hypersensitivity (such as fever or lymphadenopathy) may herald a serious medical event and that the patient should report any such occurrence to a physician immediately [see Warnings and Precautions].

Anaphylaxis and Angioedema

Advise patients to discontinue Gabapentin and seek medical care if they develop signs or symptoms of anaphylaxis or angioedema.

Dizziness and Somnolence and Effects on Driving and Operating Heavy Machinery

Advise patients that Gabapentin may cause dizziness, somnolence, and other symptoms and signs of CNS depression. Other drugs with sedative properties may increase these symptoms. Accordingly, although patients' ability to determine their level of impairment can be unreliable, advise them neither to drive a car nor to operate other complex machinery until they have gained sufficient experience on Gabapentin to gauge whether or not it affects their mental and/or motor performance adversely. Inform patients that it is not known how long this effect lasts.

Suicidal Thinking and Behavior

Counsel the patient, their caregivers, and families that AEDs, including Gabapentin, may increase the risk of suicidal thoughts and behavior. Advise patients of the need to be alert for the emergence or worsening of symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Instruct patients to report behaviors of concern immediately to healthcare providers.

Use in Pregnancy

Instruct patients to notify their physician if they become pregnant or intend to become pregnant during therapy, and to notify their physician if they are breast feeding or intend to breast feed during therapy.

10. Details of manufacturer

Refer Pack for manufacturer details.

Marketed by: **Abbott Healthcare Pvt. Ltd.**
Angel Space, Bldg. D-4, Gala No. 1 to 3 & 11 to 13 Ground Floor,
101 to 106 & 111 to 116 First Floor, 201 to 206 & 211 to 216 2nd
Floor, Pimplas, Dist. Thane, Bhiwandi-421 302, Maharashtra, India.

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11. Details of permission or licence number with date
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