

Size: 260 (L) x 420 H) mm

Folding size: 30 x 90 mm

Carton size: 46 x 22 x 106 mm

Front



PRAMIPEXOLE Dihydrochloride

PRIDEL

250 mcg & 1 mg Tablet

Anti-Parkinson Drug (Dopamine Agonist)

PRODUCT NAME:

PRIDEL

NAME AND STRENGTH:

Pramipexole Dihydrochloride Tablets 250 mcg & 1 mg

PRODUCT DESCRIPTION:

Pridel 250 mcg tablets

White to off white, round shaped, flat beveled edge uncoated tablets plain on both sides

Pridel 1 mg tablets

White to off white, round shaped, flat beveled edge uncoated tablets with breakline on one side and plain on other side

Breakline is to facilitate breaking for ease of swallowing and not for dividing into equal doses.

FORMULATION/COMPOSITION:

Each uncoated tablet contains:

Pramipexole Dihydrochloride

Monohydrate BP.....250 mcg

Pramipexole Dihydrochloride

Monohydrate BP.....1 mg

PHARMACODYNAMICS / PHARMACOKINETICS:

PHARMACODYNAMICS:

Pharmacotherapeutic group: anti-Parkinson drugs, dopamine agonists, ATC code: N04BC05

Mechanism of action

Pramipexole is a dopamine agonist that binds with high selectivity and specificity to the D2 subfamily of dopamine receptors of which it has a preferential affinity to D3 receptors, and has full intrinsic activity. Pramipexole alleviates Parkinsonian motor deficits by stimulation of dopamine receptors in the striatum. Animal studies have shown that pramipexole inhibits dopamine synthesis, release, and turnover.

The mechanism of action of pramipexole as treatment for Restless Legs Syndrome is unknown. Neuropharmacological evidence suggests primary dopaminergic system involvement.

Pharmacodynamic effects

In human volunteers, a dose-dependent decrease in prolactin was observed. In a clinical trial with healthy volunteers, where Pramipexole prolonged-release tablets were titrated faster (every 3 days) than recommended up to 3.15 mg pramipexole base (4.5 mg of salt) per day, an increase in blood pressure and heart rate was observed. Such effect was not observed in patient studies.

Clinical efficacy and safety in Parkinson's disease

In patients pramipexole alleviates signs and symptoms of idiopathic Parkinson's disease. Placebo controlled clinical trials included approximately 1,800 patients of Hoehn and Yahr stages I – V treated with pramipexole. Out of these, approximately 1,000 were in more advanced stages, received concomitant levodopa therapy, and suffered from motor complications.

In early and advanced Parkinson's disease, efficacy of pramipexole in controlled clinical trials was maintained for approximately six months. In open continuation trials lasting for more than three years there were no signs of decreasing efficacy.

In a controlled double blind clinical trial of 2 year duration, initial treatment with pramipexole significantly delayed the onset of motor complications, and reduced their occurrence compared to initial treatment with levodopa. This delay in motor complications with pramipexole should be balanced against a greater improvement in motor function with levodopa (as measured by the mean change in UPDRS-score). The overall incidence of hallucinations and somnolence was generally higher in the escalation phase with the pramipexole group. However, there was no significant difference during the maintenance phase. These points should be considered when initiating pramipexole treatment in patients with Parkinson's disease.

Paediatric population

The European Medicines Agency has waived the obligation to submit the results of studies with Pramipexole in all subsets of the paediatric population in Parkinson's Disease (see for information on paediatric use).

Clinical efficacy and safety in Restless Legs Syndrome The efficacy of pramipexole was evaluated in four placebo-controlled clinical trials in approximately 1,000 patients with moderate to very severe idiopathic Restless Legs Syndrome. The mean change from baseline in the Restless Legs Syndrome Rating Scale (IRLS) and the Clinical Global Impression-Improvement (CGI-I) were the primary efficacy outcome measures. For both primary endpoints statistically significant differences have been observed for the pramipexole dose groups 0.25 mg, 0.5 mg and 0.75 mg pramipexole salt in comparison to placebo. After 12 weeks of treatment the baseline IRLS score improved from 23.5 to 14.1 points for placebo and from 23.4 to 9.4 points for pramipexole (doses combined). The adjusted mean difference was -4.3 points (CI 95% -6.4;

-2.1 points, p-value <0.0001). CGI-I responder rates (improved, very much improved) were 51.2% and 72.0% for placebo and pramipexole, respectively (difference 20% CI 95%: 8.1%; 31.8%, p<0.0005).

Efficacy was observed with 0.088 mg of base (0.125 mg of salt) per day after the first week of treatment.

In a placebo-controlled polysomnography study over 3 weeks Pramipexole significantly reduced the number of periodic limb movements during time in bed. Longer term efficacy was evaluated in a placebo-controlled clinical trial. After 26 weeks of treatment, there was an adjusted mean reduction in IRLS total score of 13.7 and 11.1 points in the pramipexole and placebo group, respectively, with a statistically significant ($p = 0.008$) mean treatment difference of -2.6. CGI-I responder rates (much improved, very much improved) were 50.3% (80/159) and 68.5% (111/162) for placebo and pramipexole, respectively ($p = 0.001$), corresponding to a number needed to treat (NNT) of 6 patients (95%CI: 3.5, 13.4).

Paediatric population

The European Medicines Agency has deferred the obligation to submit the results of studies with Pramipexole in one or more subsets of the paediatric population in Restless Legs.

Clinical efficacy and safety in Tourette Disorder

The efficacy of pramipexole (0.0625-0.5 mg/day) with paediatric patients aged 6-17 years with Tourette Disorder was evaluated in a 6-week, double-blind, randomised, placebo-controlled flexible dose study. A total of 63 patients were randomised (43 on pramipexole, 20 on placebo). The primary endpoint was change from baseline on the Total Tic Score (TTS) of the Yale Global Tic Severity Scale (YGTSS). No difference was observed for pramipexole as compared to placebo for either the primary endpoint or for any of the secondary efficacy endpoints including YGTSS total score, Patient Global Impression of Improvement (PGI-I), Clinical Global Impression of Improvement (CGI-I), or Clinical Global Impressions of Severity of Illness (CGI-S). Adverse events occurring in at least 5% of patients in the pramipexole group and more common in the pramipexole-treated patients than in patients on placebo were: headache (27.9%, placebo 25.0%), somnolence (7.0%, placebo 5.0%), nausea (18.6%, placebo 10.0%), vomiting (11.6%, placebo 0.0%), upper abdominal pain (7.0%, placebo 5.0%), orthostatic hypotension (9.3%, placebo 5.0%), myalgia (9.3%, placebo 5.0%), sleep disorder (7.0%, placebo 0.0%), dyspnoea (7.0%, placebo 0.0%) and upper respiratory tract infection (7.0%, placebo 5.0%). Other significant adverse events leading to discontinuation of study medication for patients receiving pramipexole were confusional state, speech disorder and aggravated condition.

PHARMACOKINETICS:

Absorption: Pramipexole is rapidly and completely absorbed following oral administration. The absolute bioavailability is greater than 90% and the maximum plasma concentrations occur between 1 and 3 hours. Concomitant administration with food did not reduce the extent of pramipexole absorption, but the rate of absorption was reduced. Pramipexole shows linear kinetics and a small inter-patient variation of plasma levels.**Distribution:** In humans, the protein binding of pramipexole is very low (< 20%) and the volume of distribution is large (400 l). High brain tissue concentrations were observed in the rat (approx. 8-fold compared to plasma).**Biotransformation:** Pramipexole is metabolised in man only to a small extent.**Elimination:** Renal excretion of unchanged pramipexole is the major route of elimination. Approximately 90% of ^{14}C -labelled dose is excreted through the kidneys while less than 2% is found in the faeces. The total clearance of pramipexole is approximately 500 ml/min and the renal clearance is approximately 400 ml/min. The elimination half-life ($t_{1/2}$) varies from 8 hours in the young to 12 hours in the elderly.

INDICATION

Pramipexole is indicated in adults for treatment of the signs and symptoms of idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or "on off" fluctuations).

Pramipexole is indicated in adults for symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome in doses up to 0.54 mg of base (0.75 mg of salt)

DOSAGE AND MODE OF ADMINISTRATION:

Posology

Parkinson's disease

The daily dose is administered in equally divided doses 3 times a day.

Initial treatment: Doses should be increased gradually from a starting dose of 0.264 mg of base (0.375 mg of salt) per day and then increased every 5-7 days. Providing patients do not experience intolerable undesirable effects, the dose should be titrated to achieve a maximal therapeutic effect.

Ascending dose schedule of Pramipexole

Week	Dose (mg of base)	Total Daily Dose (mg of base)	Dose (mg of salt)	Total Daily Dose (mg of salt)
1	3 x 0.088	0.264	3 x 0.125	0.375
2	3 x 0.18	0.54	3 x 0.25	0.75
3	3 x 0.35	1.05	3 x 0.5	1.50

If a further dose increase is necessary the daily dose should be increased by 0.54 mg of base (0.75 mg of salt) at weekly intervals up to a maximum dose of 3.3 mg of base (4.5 mg of salt) per day. However, it should be noted that

the incidence of somnolence is increased at doses higher than 1.5 mg (of salt) per day.

Maintenance treatment: The individual dose of pramipexole should be in the range of 0.264 mg of base (0.375 mg of salt) to a maximum of 3.3 mg of base (4.5 mg of salt) per day. During dose escalation in pivotal studies, efficacy was observed starting at a daily dose of 1.1 mg of base (1.5 mg of salt). Further dose adjustments should be done based on the clinical response and the occurrence of adverse reactions. In clinical trials approximately 5% of patients were treated at doses below 1.1 mg of base (1.5 mg of salt). In advanced Parkinson's disease, pramipexole doses higher than 1.1 mg of base (1.5 mg of salt) can be useful in patients where a reduction of the levodopa therapy is intended. It is maintenance treatment with Pramipexole, depending on reactions in individual patients.**Treatment discontinuation:** Abrupt discontinuation of dopaminergic therapy can lead to the development of a neuroleptic malignant syndrome. Pramipexole should be tapered off at a rate of 0.54 mg of base (0.75 mg of salt) per day until the daily dose has been reduced to 0.54 mg of base (0.75 mg of salt). Thereafter the dose should be reduced by 0.264 mg of base (0.375 mg of salt) per day.**Renal impairment:** The elimination of pramipexole is dependent on renal function. The following dose schedule is suggested for initiation of therapy: Patients with a creatinine clearance above 50 ml/min require no reduction in daily dose or dosing frequency.

In patients with a creatinine clearance between 20 and 50 ml/min, the initial daily dose of Pramipexole should be administered in two divided doses, starting at 0.088 mg of base (0.125 mg of salt) twice a day (0.176 mg of base/0.25 mg of salt daily). A maximum daily dose of 1.57 mg pramipexole base (2.25 mg of salt) should not be exceeded.

In patients with a creatinine clearance less than 20 ml/min, the daily dose of Pramipexole should be administered in a single dose, starting at 0.088 mg of base (0.125 mg of salt) daily. A maximum daily dose of 1.1 mg pramipexole base (1.5 mg of salt) should not be exceeded.

If renal function declines during maintenance therapy the Pramipexole daily dose should be reduced by the same percentage as the decline in creatinine clearance, i.e. if creatinine clearance declines by 30%, then the Pramipexole daily dose should be reduced by 30%. The daily dose can be administered in two divided doses if creatinine clearance is between 20 and 50 ml/min and as a single daily dose if creatinine clearance is less than 20 ml/min.

Hepatic impairment: Dose adjustment in patients with hepatic failure is probably not necessary, as approx. 90% of absorbed active substance is excreted through the kidneys. However, the potential influence of hepatic insufficiency on Pramipexole pharmacokinetics has not been investigated.**Paediatric population:** The safety and efficacy of Pramipexole in children below 18 years has not been established.

There is no relevant use of Pramipexole in the paediatric population for the indication of Parkinson's disease.

Restless Legs Syndrome: The recommended starting dose of Pramipexole is 0.088 mg of base (0.125 mg of salt) taken once daily 2-3 hours before bedtime. For patients requiring additional symptomatic relief, the dose may be increased every 4-7 days to a maximum of 0.54 mg of base (0.75 mg of salt) per day.

Dose Schedule of Pramipexole		
Titration Step	Once Daily Evening Dose (mg of base)	Once Daily Evening Dose (mg of salt)
1	0.088	0.125
2*	0.18	0.25
3*	0.35	0.50
4*	0.54	0.75

* if needed

Patient's response should be evaluated after 3 months treatment and the need for treatment continuation should be reconsidered. If treatment is interrupted for more than a few days it should be re-initiated by dose titration carried out as above.

Treatment discontinuation: Since the daily dose for the treatment of Restless Legs Syndrome will not exceed 0.54 mg of base (0.75 mg of salt) Pramipexole can be discontinued without tapering off. In a 26 week placebo controlled trial, rebound of RLS symptoms (worsening of symptom severity as compared to baseline) was observed in 10% of patients (14 out of 135) after abrupt discontinuation of treatment. This effect was found to be similar across all doses.**Renal impairment:** The elimination of pramipexole is dependent on renal function. Patients with a creatinine clearance above 20 ml/min require no reduction in daily dose.

The use of Pramipexole has not been studied in haemodialysis patients, or in patients with severe renal impairment.

Hepatic impairment: Dose adjustment in patients with hepatic failure is not required, as approx. 90% of absorbed active substance is excreted through the kidneys.**Paediatric population:** Pramipexole is not recommended for use in children and adolescents below 18 years due to a lack of data on safety and efficacy.

Tourette Disorder

Paediatric population: Pramipexole is not recommended for use in children and adolescents below 18 years since the efficacy and safety has not been established in this population. Pramipexole should not be used in children or adolescents with Tourette Disorder because of a negative benefit-risk balance for this disorder.**Method of administration:** The tablets should be taken orally, swallowed with water, and can be taken either with or without food.

CONTRAINDICATION & PRECAUTION(S), WARNING(S):

Hypersensitivity to the active substances or to any of the excipients

PRECAUTIONS & WARNING:

When prescribing Pramipexole in a patient with Parkinson's disease with renal impairment a reduced dose is suggested.

Hallucinations

Hallucinations are known as a side effect of treatment with dopamine agonists and levodopa. Patients should be informed that (mostly visual) hallucinations can occur.

Dyskinesia

In advanced Parkinson's disease, in combination treatment with levodopa, dyskinesia can occur during the initial titration of Pramipexole. If they occur, the dose of levodopa should be decreased.

Sudden onset of sleep and somnolence

Pramipexole has been associated with somnolence and episodes of sudden sleep onset, particularly in patients with Parkinson's disease. Sudden onset of sleep during daily

Size: 260 (L) x 420 (H) mm

Folding size: 30 x 90 mm

Carton size: 46 x 22 x 106 mm

↓ Back

The excretion of pramipexole into breast milk has not been studied in women. In rats, the concentration of active substance-related radioactivity was higher in breast milk than in plasma.
In the absence of human data, Pramipexole should not be used during breast-feeding. However, if its use is unavoidable, breast-feeding should be discontinued.
Fertility: No studies on the effect on human fertility have been conducted. In animal studies, pramipexole affected oestrous cycles and reduced female fertility as expected for a dopamine agonist. However, these studies did not indicate direct or indirect harmful effects with respect to male fertility.

INTERACTIONS :**Plasma protein binding**

Pramipexole is bound to plasma proteins to a very low (< 20%) extent, and little biotransformation is seen in man. Therefore, interactions with other medicinal products affecting plasma protein binding or elimination by biotransformation are unlikely. As Anticholinergics are mainly eliminated by biotransformation, the potential for an interaction is limited, although an interaction with Anticholinergics has not been investigated. There is no pharmacokinetic interaction with selegiline and levodopa.

Inhibitors/competitors of active renal elimination pathway

Cimetidine reduced the renal clearance of pramipexole by approximately 34%, presumably by inhibition of the cationic secretory transport system of the renal tubules. Therefore, medicinal products that are inhibitors of this active renal elimination pathway or are eliminated by this pathway, such as cimetidine, amantadine, mexiletine, zidovudine, cisplatin, quinine, and procainamide, may interact with pramipexole resulting in reduced clearance of pramipexole. Reduction of the pramipexole dose should be considered when these medicinal products are administered concomitantly with Pramipexole.

Combination with levodopa

When Pramipexole is given in combination with levodopa, it is recommended that the dose of levodopa is reduced and the dose of other anti-Parkinsonian medicinal products is kept constant while increasing the dose of Pramipexole. Because of possible additive effects, caution should be advised when patients are taking other sedating medicinal products or alcohol in combination with pramipexole.

Antipsychotic medicinal products

Co-administration of antipsychotic medicinal products with pramipexole should be avoided, e.g. if antagonistic effects can be expected.

ADVERSE EFFECTS:

Based on the analysis of pooled placebo-controlled trials, comprising a total of 1,923 patients on pramipexole and 1,354 patients on placebo, adverse drug reactions were frequently reported for both groups. 63% of patients on pramipexole and 52% of patients on placebo reported at least one adverse drug reaction.

The majority of adverse drug reactions usually start early in therapy and most tends to disappear even as therapy is continued.

Within the system organ classes, adverse reactions are listed under headings of frequency (number of patients expected to experience the reaction), using the following categories: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$); not known (cannot be estimated from the available data).

Parkinson's disease, most common adverse reactions

The most commonly ($\geq 5\%$) reported adverse drug reactions in patients with Parkinson's disease more frequent with pramipexole treatment than with placebo were nausea, dyskinesia, hypotension, dizziness, somnolence, insomnia, constipation, hallucination, headache and fatigue. The incidence of somnolence is increased at doses higher than 1.5 mg pramipexole salt per day. A more frequent adverse drug reaction in combination with levodopa was dyskinesia. Hypotension may occur at the beginning of treatment, especially if pramipexole is titrated too fast.

Body System	Very common ($\geq 1/10$)	Common ($\geq 1/100$ to $< 1/10$)	Uncommon ($\geq 1/1,000$ to < 1/100)	Rare ($\geq 1/10,000$ to < 1/1,000)	Not known
Infections and infestations			pneumonia		
Endocrine disorders			inappropriate antidiuretic hormone secretion ¹		
Psychiatric disorders		Insomnia hallucinations abnormal dreams confusion behavioural symptoms of impulse control disorders and compulsions	compulsive shopping pathological gambling restlessness hyper sexuality delusion libido disorder paranoia delirium binge eating ¹ hyperphagia ¹	mania	
Nervous system disorders	somnolence dizziness dyskinesia	headache	sudden onset of sleep amnesia hyperkinesia syncope		
Eye disorders		visual impairment including diplopia vision blurred visual acuity reduced			
Cardiac disorders			cardiac failure ¹		
Vascular disorders		hypotension			
Respiratory, thoracic, and mediastinal disorders			Dyspnoea hiccups		
Gastrointestinal disorders	nausea	constipation vomiting			
Skin and subcutaneous tissue disorders			hypersensitivity pruritus rash		
General disorders and administration site conditions		fatigue peripheral oedema		Dopamine agonist withdrawal syndrome including apathy, anxiety, depression, fatigue, sweating and pain.	
Investigations		weight decrease including decreased appetite	weight increase		

¹This side effect has been observed in post-marketing experience. With 95 % certainty, the frequency category is not greater than uncommon, but might be lower. Precise frequency estimation is not possible as the side effect did not occur in a clinical trial database of 2,762 patients with Parkinson's disease treated with pramipexole.

Restless Legs Syndrome, most common adverse reactions

The most commonly ($\geq 5\%$) reported adverse drug reactions in patients with Restless Legs Syndrome treated with pramipexole were nausea, headache, dizziness and fatigue. Nausea and fatigue were more often reported in female patients treated with PRAMIPEXOLE (20.8% and 10.5%, respectively) compared to males (6.7% and 7.3%, respectively).

Table 2: Restless Legs Syndrome

Body System	Very common ($\geq 1/10$)	Common ($\geq 1/100$ to < 1/10)	Uncommon ($\geq 1/1,000$ to < 1/100)	Not known
Infections and infestations			pneumonia ¹	
Endocrine disorders			inappropriate antidiuretic hormone secretion ¹	

Psychiatric disorders		insomnia abnormal dreams	restlessness confusion hallucinations libido disorder delusion ¹ hyperphagia ¹ paranoia ¹ mania ¹ delirium ¹ behavioural symptoms of impulse control disorders and compulsions ¹ (such as: compulsive shopping, pathological gambling, hyper sexuality, binge eating)	
Nervous system disorders		headache dizziness somnolence	sudden onset of sleep syncope dyskinesia amnesia ¹ hyperkinesia ¹	
Eye disorders			visual impairment including visual acuity reduced diplopia vision blurred	
Cardiac disorders			cardiac failure ¹	
Vascular disorders			hypotension	
Respiratory, thoracic, and mediastinal disorders			dyspnoea hiccups	
Gastrointestinal disorders	nausea	constipation vomiting		
Skin and subcutaneous tissue disorders			hypersensitivity pruritus rash	
General disorders and administration site conditions		fatigue	peripheral oedema	Dopamine agonist withdrawal syndrome including apathy, anxiety, depression, fatigue, sweating and pain
Investigations		weight decrease including decreased appetite	weight increase	

¹This side effect has been observed in post-marketing experience. With 95 % certainty, the frequency category is not greater than uncommon, but might be lower. Precise frequency estimation is not possible as the side effect did not occur in a clinical trial database of 1,395 patients with Restless Legs Syndrome treated with pramipexole.

Description of selected adverse reactions

Somnolence Pramipexole is commonly associated with somnolence and has been associated uncommonly with excessive daytime somnolence and sudden sleep onset episodes.

Libido disorders

Pramipexole may uncommonly be associated with libido disorders (increased or decreased).

Impulse control disorders

Pathological gambling, increased libido, hyper sexuality, compulsive spending or buying, binge eating and compulsive eating can occur in patients treated with dopamine agonists including Pramipexole.

In a cross-sectional, retrospective screening and case-control study including 3,090 Parkinson's disease patients, 13.6% of all patients receiving dopaminergic or non-dopaminergic treatment had symptoms of an impulse control disorder during the past six months. Manifestations observed include pathological gambling, compulsive shopping, binge eating, and compulsive sexual behaviour (hyper sexuality). Possible independent risk factors for impulse control disorders included dopaminergic treatments and higher doses of dopaminergic treatment, younger age (≤ 65 years), not being married and self-reported family history of gambling behaviours.

Dopamine agonist withdrawal syndrome

Non-motor adverse effects may occur when tapering or discontinuing dopamine agonists including pramipexole.

Symptoms include apathy, anxiety, depression, fatigue, sweating and pain.

Cardiac failure

In clinical studies and post-marketing experience cardiac failure has been reported in patients with pramipexole. In a pharmacoepidemiological study pramipexole use was associated with an increased risk of cardiac failure compared with non-use of pramipexole (observed risk ratio 1.86; 95% CI, 1.21-2.85).

OVERDOSE AND TREATMENT:

There is no clinical experience with massive overdose. The expected adverse reactions would be those related to the Pharmacodynamic profile of a dopamine agonist, including nausea, vomiting, hyperkinesia, hallucinations, agitation and hypotension. There is no established antidote for overdose of a dopamine agonist. If signs of central nervous system stimulation are present, a neuroleptic agent may be indicated. Management of the overdose may require general supportive measures, along with gastric lavage, intravenous fluids, administration of activated charcoal and electrocardiogram monitoring.

STORAGE CONDITION:

Store at temperature not exceeding 30°C

DOSAGE FORMS AND PACKAGING AVAILABLE:

Dosage Form: Tablet
Packaging : Pridel 250 mcg & Pridel 1 mg are packed in Alu/Alu blister pack of 10's (Box of 30's)

INSTRUCTIONS AND SPECIAL PRECAUTIONS FOR HANDLING AND DISPOSAL (IF APPLICABLE):

Not Applicable

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:

Marketing Authorization Holder
Brown & Burk Philippines Inc
U-501, 5/F, SEDCCO 1 Bldg., 120 Rada cor., Legaspi Sts., Legaspi Village, Makati City, Philippines

NAME AND ADDRESS OF MANUFACTURER:

MICRO LABS LIMITED
92, Sipcot Industrial Complex,
Hosur-635 126 (T.N), India

CAUTION STATEMENT:

FOODS, DRUGS, DEVICES, AND COSMETICS ACT PROHIBITS DISPENSING WITHOUT PRESCRIPTION .

ADR REPORTING STATEMENT:

FOR SUSPECTED ADVERSE DRUG REACTION, REPORT TO THE FDA: www.fda.gov.ph

Seek medical attention immediately at the first sign of Adverse Drug Reaction.

REGISTRATION NUMBER:

Pridel 250 mcg : DR-XY47632
Pridel 1 mg : DR-XY47631

DATE OF FIRST AUTHORIZATION:

23 December 2021

DATE OF REVISION OF PACKAGE INSERT:

January 2022

EXG-ML01I-1751

420 mm

260 mm

MICRO LABS LIMITED, BANGALORE, INDIA							
1	Product Name	Pridel		Colours Used			
2	Strength	250 mcg and 1 mg		<input checked="" type="checkbox"/> BLACK <input type="checkbox"/> Keylines			
3	Component	Leaflet					
4	Category	Export - Philippines					
5	Dimension	260 x 420 mm					
6	Artwork Code	EXG-ML01I-1751					
7	Pharma Code	N/A					
8	Reason for Change	New Artwork					
Prepared by (DTP)		Checked by (PD)	Approved by				
Sign	Kanthalraju L.		Head CQA	Head Production/ Packing (Site)	Head QC (Site)		
Date	31-01-2022				Head QA (Site)		