Front

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SAP Code
OCR 10 BT (9 pt.)
132805

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

TAMBOCOR CR 100 (controlled release capsule)
TAMBOCOR CR 200 (controlled release capsule)
Flecainide acetate
Sugar free.

Read all of this leaflet carefully before you start taking TAMBOCOR CR
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TAMBOCOR CR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TAMBOCOR CR is and what it is used for
2. What you need to know before you take TAMBOCOR CR
3. How to take TAMBOCOR CR
4. Possible side effects
5. How to store TAMBOCOR CR
6. Contents of the pack and other information

1. What TAMBOCOR CR is and what it is used for
TAMBOCOR CR is a cardiac medicine. Flecainide belongs to the group of medicines that work against cardiac dysrhythmia (known as anti-dysrhythmics). It inhibits stimulus conduction in the heart and extends the time during which the heart is at rest, causing the heart to pump normally again.
TAMBOCOR CR is used to regulate the rate and rhythm of the heart.

2. What you need to know before you take TAMBOCOR CR
Do not take TAMBOCOR CR if:
- you are hypersensitive (allergic) to flecainide acetate or any of the other ingredients of TAMBOCOR CR (listed in section 6)
- you suffer from another heart condition, different from the heart condition for which you are taking this medicine (e.g., heart attack, heart failure or heart block (missed heart beats). If you are unsure, or if you would like additional information, consult your doctor or pharmacist.

TAMBOCOR CR is generally not recommended in combination with medicine belonging to class I anti-dysrhythmics, e.g., quinidine, procainamide.

Warnings and precautions

Special care should be taken with TAMBOCOR CR:
- if you have pre-existing dysrhythmia (irregular heartbeat)
- if you have a history of heart failure
- if you have a permanent pacemaker or temporary pacing electrodes
- if you suffer from reduced liver function and/or reduced kidney function since the concentration of TAMBOCOR CR in the blood may increase. In that event, your doctor may regularly have the concentration of TAMBOCOR CR in the blood checked
- if you have pre-existing conduction disorders in the heart
- if you have too little magnesium in the blood
- if you suffer from severe bradycardia (very slow heartbeat) or distinct low blood pressure. These conditions should be corrected before using TAMBOCOR CR
- if you have suffered from cardiac dysrhythmias after heart surgery
- a lowered or elevated level of potassium in the blood may influence the effect of TAMBOCOR CR. Diuretics, medicines that stimulate bowel movement (laxatives) and adrenal cortex hormones (corticosteroids) may lower the level of potassium in the blood. In that event, your doctor may have the amount of potassium in your blood checked.

Children
TAMBOCOR CR is not recommended in children under 18 years of age.

Other medicines and TAMBOCOR CR
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
If you use certain other medicines along with TAMBOCOR CR, the medicines can sometimes affect the way each other works and/or their side effects (i.e. there may be interactions).
Please consult your doctor, pharmacist or other healthcare professional, for advice if you are taking:
- Any other medicine used to regulate rate and rhythm of the heart
- Medicines that slow down heart rate and/or conduction such as beta-blockers such as propranolol, amiodarone, verapamil, diltiazem, local anaesthetics
- Digoxin (a medicine to stimulate the heart)
- Cimetidine (medicine used to treat stomach ulcers)
- Diuretics, laxatives (medicines that stimulate bowel movement) and adrenal cortex hormones (corticosteroids): your doctor may have the amount of potassium in your blood checked
- Fluoxetine, paroxetine and certain other antidepressants named "tricyclic antidepressants"
- Phenytoin, phenobarbital and carbamazepine (medicines against epilepsy): the breakdown of flecainide may be accelerated by these substances
- Clozapine (to treat psychotic disorders)
- Mizolastine and terfenadine (medicines against allergies)
- Quinine (medicine against malaria)
- Ritonavir, lopinavir and indinavir (medicines to treat HIV-infections)
- Bupropion (anti-smoking medicine).

Pregnancy and breastfeeding
Do not take TAMBOCOR CR if you are pregnant or breastfeeding.
If you are pregnant or breastfeeding your baby while taking TAMBOCOR CR, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machines
It is not always possible to predict to what extent TAMBOCOR CR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TAMBOCOR CR affects them.
If you suffer from side effects such as dizziness, double vision or blurred vision, or if you feel light in the head, then your ability to react may be reduced. This may be dangerous in situations that demand concentration and attentiveness, such as using the road, handling dangerous machinery or working at heights.

3. How to take TAMBOCOR CR
Do not share medicines prescribed for you with any other person.
Always take TAMBOCOR CR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The usual starting dose is between 100 mg to 200 mg per day, depending on your condition.
Your doctor will prescribe a personalised dose, adjusted to fit your condition. Treatment with flecainide will normally be started under medical supervision (if necessary, in the hospital).

If you take more TAMBOCOR CR than you should:
Overdosage with TAMBOCOR CR is a potentially life-threatening medical emergency. In the event of overdosage, contact your doctor or go to the nearest hospital or poison control centre immediately.

If you forget to take TAMBOCOR CR
Do not take a double dose to make up for forgotten individual doses.

If you stop taking TAMBOCOR CR
If you suddenly stop taking TAMBOCOR CR the cardiac dysrhythmia will no longer be controlled as intended. So never stop using it without your doctor knowing.

4. POSSIBLE SIDE EFFECTS
TAMBOCOR CR can have the following side effects.
Not all side effects reported for TAMBOCOR CR are included in this leaflet. Should your general health worsen or if you experience untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Frequent side effects:
- feeling dizzy
- lightheaded
- double vision, vision impairment or blurring of vision
- more frequent occurrence of pre-existing arrhythmia (irregular heartbeat)
- shortness of breath
- weakness; fatigue
- fever
- fluid in the tissues (oedema).

Less frequent side effects:
- an abnormal sensation, typically tingling or pricking ('pins and needles')
- difficulty in controlling movements (ataxia)
- a partial or total loss of sensation in a part of your body
- abnormally excessive sweating
- fainting or passing out
- a rhythmic shaking movement in one or more parts of your body (tremors)
- flushing
- sleepiness, headache
- weakness, numbness and pain, usually in your hands and feet
- seizures
- involuntary, erratic, writhing movements of the face, arms, legs or trunk (dyskinesia)
- irregular heartbeat with increased heartbeat
- inflammation of lung tissue; lung disease that occurs when lung tissue becomes damaged and scarred
- nausea, vomiting, constipation, abdominal pain, decreased appetite, diarrhoea, indigestion, flatulence
- yellowing of the skin (jaundice)
- liver failure
- allergic skin reactions, including rash and hair loss
- sensitivity to the effects of sunlight
- joint and muscle pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TAMBOCOR CR.

5. How to store TAMBOCOR CR
Store the capsules in a cool, dry place at or below 25 °C.
In order to protect from light, keep blister pack in the outer carton.
Keep all medicines out of the reach and sight of children.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TAMBOCOR CR contains
The active substance is flecainide.
The other ingredients are microcrystalline cellulose, methacrylic acid – methyl methacrylate copolymer (1:2), polyethylene glycol 400 (Macrogol 400), talc, gelatin, titanium oxide, iron oxide black, erythrosine, shellac.

What TAMBOCOR CR looks like and contents of the pack
TAMBOCOR CR 100: Hard, white to off-white beadlets in size 3 hard gelatin capsule with a light grey cap and an opaque white body, printed TR on the cap and 100 on the body, in black.
TAMBOCOR CR 200: Hard, white to off-white beadlets in size 1 hard gelatin capsule with a light grey cap and an opaque pink body, printed TR on the cap and 200 on the body, in black.

TAMBOCOR CR are controlled release capsules and are packed in:
Blister packs of 15, 30 and 60 capsules.
Blisters are made of clear UPVC / PVC with aluminium foil backing.

Holder of Certificate of Registration
iNova Pharmaceuticals (Pty) Ltd, 15E Riley Road, Bedfordview, South Africa.
Tel: +27 (0)11 087 0000

This leaflet was last revised on
05 September 2021

Registration number
TAMBOCOR CR 100: 37/6.2/0199
TAMBOCOR CR 200: 37/6.2/0201
TAMBOCOR CR 50: 37/6.2/0198
TAMBOCOR CR 150: 37/6.2/0200

Access to the corresponding Professional Information
Full professional information can be found at www.inovapharma.co.za or can be obtained upon request from iNova Pharmaceuticals (Pty) Ltd.

CODE: GLU/DRUGS/G-1430

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132805

200 MM

SAP Code

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Die Line Number: TD 047.01
Die Line Description : Die line of Tambocore CR 50, Tambacore CR 100, Tambacore CR 150 & Tambacore CR 200 capsules (South Africa)

TEXT AREA

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SAP Code
132805

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S4

TAMBOCOR CR 100 (kapsule met beheerde vrystelling)
TAMBOCOR CR 200 (kapsule met beheerde vrystelling)
Flekaïniedasetaat
Suikervry.

Lees hierdie hele blad noukeurig deur voordat u begin om TAMBOCOR CR te drink.
- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- TAMBOCOR CR is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

Wat in hierdie blad is.

1. Waarvoor TAMBOCOR CR gebruik word
2. Wat u moet weet voordat u TAMBOCOR CR drink
3. Hoe om TAMBOCOR CR te drink
4. Moontlike newe-effekte
5. Hoe om TAMBOCOR CR te bêre
6. Inhoud van die pak en ander inligting

1. Waarvoor TAMBOCOR CR gebruik word.
TAMBOCOR CR is hartmedisyne. Flekaïnied behoort aan die groep medisyne wat teen hartdisritmie werk (bekend as antidisritmiese middels). Dit rem stimulusgeleiding in die hart en verleng die tyd waarin die hart rus, wat veroorsaak dat die hart weer normaal pomp.
TAMBOCOR CR word gebruik om die tempo en ritme van die hart te reguleer.

2. Wat u moet weet voordat u TAMBOCOR CR drink.
Moenie TAMBOCOR CR gebruik nie as u:
- hipersensitief (allergies) vir flekaïniedasetaat of vir enige van die ander bestanddele van TAMBOCOR CR (gelys in afdeling 6) is
- aan 'n ander harttoestand ly, anders as die harttoestand waarvoor u hierdie medisyne gebruik [bv. hartaanval, hartversaking of hartblok (oorgeslane hartklop)]. Raadpleeg u dokter of apteker as u onseker is of meer inligting wil hê.

Oor die algemeen word TAMBOCOR CR nie in kombinasie met medisyne van klas I-antidisritmiese middels, bv. kinidien, prokaïenamied aanbeveel, nie.

Waarskuwings en voorsorgmaatreëls.

Wees besonder versigtig met TAMBOCOR CR:
- as u 'n bestaande disritmie (onreëlmatige hartklop) het
- as u 'n geskiedenis van hartversaking het
- as u 'n permanente pasaangeër of tydelike elektrodes het
- as u swak lewerfunksie en/of swak nierfunksie het, aangesien die konsentrasie van TAMBOCOR CR in die bloed kan styg. In hierdie geval moet u dokter die konsentrasie van TAMBOCOR CR in die bloed dalk gereeld laat toets
- as u bestaande geleidingsversteurings in die hart het
- as u te min magnesium in die bloed het
- as u aan erge bradikardie (baie stadige hartklop) ly of duidelike lae bloeddruk het. Hierdie toestande moet reggestel word voordat TAMBOCOR CR gebruik word
- as u hartdisritmie na 'n hartoperasie gehad het
- lae of hoë vlakke kalium in die bloed kan die effek van TAMBOCOR CR beïnvloed. Diuretika, medisyne wat die dermbeweging stimuleer (lakseermiddels) en hormone van die byniere (kortikosteroïede) kan die kaliumvlak in die bloed verlaag. In hierdie geval kan u dokter die hoeveelheid kalium in u bloed laat toets.

Kinders.
TAMBOCOR CR word nie vir kinders jonger as 18 jaar aanbeveel nie.

Ander medisyne en TAMBOCOR CR.
Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik. (Dit sluit alle aanvullende en tradisionele medisyne in.)
As u sekere ander medisyne saam met TAMBOCOR CR gebruik, kan die medisyne soms mekaar se werking en/of die newe-effekte daarvan beïnvloed (d.w.s. daar kan interaksies wees).
Raadpleeg u dokter, apteker of ander gesondheidskundige asseblief vir advies as u die volgende gebruik:
- Enige ander medisyne wat gebruik word om hartklop en -ritme te reguleer
- Medisyne wat hartklop en/of geleiding vertraag, soos beta-blokkers soos propranolol, amiodaroon, verapamiel, diltiasem, lokale verdowers
- Digoksien (medisyne om die hart te stimuleer)
- Simetidien (om maagsere te behandel)
- Diuretika, lakseermiddels (medisyne wat dermbeweging stimuleer) en bynierhormone (kortikosteroïede): u dokter kan die hoeveelheid kalium in u bloed laat toets
- Fluoksetien, paroksetien en sekere ander antidepressante met die naam "trisikliese antidepressante"
- Fenitoïen, fenobarbitoon en karbaamasepien (medisyne teen epilepsie): die afbreek van flekaïnied kan deur hierdie stowwe versnel word
- Klosapien (vir psigotiese afwykings)
- Misolastien en terfenadien (medisyne teen allergieë)
- Kinien (medisyne teen malaria)
- Ritonavir, lopinavir en indinavir (medisyne vir die behandeling van MIV-infeksies)
- Bupropioon (anti-rookmedisyne).

Swangerskap en borsvoeding.
Moenie TAMBOCOR CR gebruik as u swanger is of borsvoed nie.
As u swanger is of borsvoed of dink dat u dalk swanger kan wees, moet u u dokter, apteker of ander gesondheidspraktisyn om advies raadpleeg voordat u hierdie medisyne gebruik.

Motorbestuur en gebruik van masjinerie.
Dit is nie altyd moontlik om te voorspel tot watter mate TAMBOCOR CR met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet sorg dat hulle, totdat hulle weet hoe TAMBOCOR CR hulle beïnvloed, nie aan bogenoemde aktiwiteite deelneem nie.
As u newe-effekte het, soos duiseligheid, dubbelvisie of dowwe sig, of as u lighoofdig voel, kan u reaksievermoë aangetas word. Dit kan gevaarlik wees in situasies wat konsentrasie en aandag vereis, soos ry op 'n pad, die hantering van gevaarlike masjinerie of die werk op hoogtes.

3. Hoe om TAMBOCOR CR te drink.
Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.
Drink TAMBOCOR CR altyd presies soos wat u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.
Die gewone aanvangsdosis is tussen 100 mg en 200 mg per dag, afhangende van u toestand.
U dokter sal 'n persoonlike dosis volgens u toestand vir u voorskryf.
Behandeling met flekaïnied begin gewoonlik onder mediese toesig (indien nodig, in die hospitaal).

As u meer TAMBOCOR CR gedrink het as wat u moes:
Oordosering met TAMBOCOR CR is 'n mediese noodgeval wat potensieel lewensgevaarlik is. In die geval van oordosering, raadpleeg u dokter of gaan onmiddellik na die naaste hospitaal of gifsentrum.

As u vergeet om TAMBOCOR CR te drink.
Moenie 'n dubbele dosis gebruik om vir vergete individuele dosisse op te maak nie.

As u ophou om TAMBOCOR CR te drink.
As u skielik ophou om TAMBOCOR CR te drink, word hartdisritmie nie meer soos bedoel beheer nie. Moet dus nooit ophou om dit te gebruik sonder dat u dokter dit weet nie.

4. MOONTLIKE NEWE-EFFEKTE.
TAMBOCOR CR kan die volgende newe-effekte hê.
Nie al die newe-effekte wat vir TAMBOCOR CR aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand vererger of as u newe-effekte ervaar terwyl u hierdie medisyne gebruik, moet u u dokter, apteker of ander gesondheidspraktisyn om advies raadpleeg.

Newe-effekte wat dikwels voorkom:
- voel duiselig
- lighoofdigheid
- dubbelvisie, gesiggestremdheid of dowwe visie
- bestaande aritmie (onreëlmatige hartklop) kom meer dikwels voor
- kortasemheid
- swakheid, moegheid
- koors
- vloeistof in die weefsels (edeem).

Newe-effekte wat minder dikwels voorkom:
- 'n abnormale gevoel, tipies tintelend of prikkelend (naalde en spelde)
- probleme met die beheer van beweging (ataksie)
- gedeeltelike of totale verlies aan sensasie in 'n deel van die liggaam
- abnormale oormatige sweet
- flou word of floutes
- 'n ritmiese skudbeweging in een of meer dele van die liggaam (bewing)
- blosing
- slaperigheid, hoofpyn
- swakheid, gevoelloosheid en pyn, gewoonlik in die hande en voete
- toevalle/stuipe (versteuring van die senuweestelsel)
- onwillekeurige, wisselvallige, kronkelende bewegings van die gesig, arms, bene of romp (diskinesie)
- onreëlmatige hartklop met vinniger hartklop
- ontsteking van die longweefsel, longsiekte wat voorkom wanneer longweefsel beskadig of beseer word
- naarheid, braking, hardlywigheid, buikpyn, swak eetlus, diarree, dispepsie, winderigheid
- geel verkleuring van die vel (geelsug)
- lewerversaking
- allergiese velreaksies, waaronder veluitslag en haarverlies
- gevoeligheid vir die effek van sonlig
- gewrigs- en spierpyn.

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte.
Praat met u dokter of apteker as u newe-effekte ervaar. U kan newe-effekte ook by SAROGP (SAHPRA) aanmeld via die **"6.04 Adverse Drug Reaction Reporting Form"** wat aanlyn by SAHPRA se publikasies gekry kan word: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van TAMBOCOR CR te gee.

5. Hoe om TAMBOCOR CR te bêre.
Bêre die kapsules op 'n koel, droë plek by of onder 25 ºC.
Hou die stulpstrook in die buitenste karton om teen lig te beskerm.
Hou alle medikasie buite bereik en sig van kinders.
Gee alle ongebruikte medisyne terug aan u apteker.
Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

6. Inhoud van die pak en ander inligting.

Wat TAMBOCOR CR bevat.
Die aktiewe bestanddeel is flekaïnied.
Die ander bestanddele is mikrokristallyne sellulose, metakrielsuur-metielmetakrilaatkopolimeer (1: 2), poliëtileenglikol 400 (Macrogol 400), talk, gelatien, titaanoksied, swart ysteroksied, eritrosien, skellak.

Hoe TAMBOCOR CR lyk en die inhoud van die pakkie.
TAMBOCOR CR 100: Harde, wit tot naaswit krale in hardegelatienkapsules van grootte 3 met 'n liggrys dop en 'n ondeursigtige wit romp, met TR in swart op die dop en 100 op die romp gedruk.
TAMBOCOR CR 200: Harde, wit tot naaswit krale in hardegelatienkapsules van grootte 1 met 'n liggrys dop en 'n ondeursigtige pienk romp, met TR in swart op die dop en 200 op die romp gedruk.
TAMBOCOR CR is kapsules met beheerde vrystelling en verpak in:
Stulpstroke wat 15, 30 of 60 kapsules bevat.
Stulpstroke is van deursigtige UPVC/PVDC met aluminiumrugkante gemaak.

Houer van die registrasiesertifikaat.
iNova Pharmaceuticals (Pty) Ltd, Rileyweg 15E, Bedfordview, Suid-Afrika

Tel: +27 (0)11 087 0000

Hierdie blad is laas hersien op.
05 September 2021

Registrasienommer.
TAMBOCOR CR 100: 37/6.2/0199
TAMBOCOR CR 200: 37/6.2/0201
TAMBOCOR CR 50: 37/6.2/0198
TAMBOCOR CR 150: 37/6.2/0200

Toegang tot die ooreenstemmende Professionele Inligting vir Gesondheidspraktisyn.
Volledige professionele inligting kan op www.inovapharma.co.za of op aanvraag van iNova Pharmaceuticals gekry word.

CODE: GLU/DRUGS/G-1430

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200 MM

SAP Code

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2.62 mm **PATIENT INFORMATION LEAFLET**

2.62 mm **SCHEDULING STATUS** S4

2.62 mm **TAMBOCOR CR 100** (controlled release capsule)
TAMBOCOR CR 200 (controlled release capsule)
Flecainide acetate
Sugar free.

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2.62 mm 6204 2564 1

DocuSigned by:
Izzatul Hidayah
Signer Name: Izzatul Hidayah
Signing Reason: I approve this document
Signing Time: 13-Apr-2022 | 19:51 AEST
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GROUP 24|7 WORLDWIDE™ inova pharmaceuticals

ARTWORK

Job No. : JB-02616 V7
UIC : A5998
SKU : 100473 100474
A5998_TAMBOCOR 100MG & 200MG CR CAP 30 (SHARED)
Component : LEAFLET
Country: SA

22.12.21 - V0 - Artwork build - Chanon
18.01.22 - V1 - Amend - Chanon
03.02.22 - V2 - Amend - Chanon
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30.03.22 - V5 - Amend - Koragot
31.03.22 - V6 - Amend - Koragot
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G247 File Name: 95590_A5998_TAMBOCOR 100MG & 200MG CR CAP 30 (SHARED)_SA_LT_FA

Colour 100% — PMS Black C

Guide

Colour Not to print

SAP Code: 132805	Country : South Africa	Mfg. Location : Panoli TI 10	Product Name : TAMBOCOR CR 100 & 200 mg
Packaging Material : Leaflet	Existing / Reference Art : 126589	Version No.: 1	Date : 13-04-2022
Dimension : 600 x 200 mm (±1 mm)		Size After Folding : 200 x 25 mm (±1 mm)	Core Dia : NA
Reel Dia : NA	Varnish / Lamination : NA	Roll Unwind Direction : NA	Print Repeat Length : NA
Packaging Material Specification (For Supplier only) : ITC fine print paper		Colours: Pantone Balck C	Folding Pattern : 2 Vertical Folds 3 Horizontal Folds
Grammage: 40 GSM ± 5%			
Thickness : NA			
Other Test : NA			
Reason for Change : Change in text matter as per marketing requirement			J. B. CHEMICALS & PHARMACEUTICALS LTD.
File Path : X:\Artwork\Prasad\Aus. South Africa\TAMBOCOR 100 & 200 mg - Leaflet\Open File\132805 TAMBOCOR 100MG _ 200MG CR CAP 30 (SHARED) 95590 A5998 - LT - SA.ai			

Artist : Datta Bali	Initiated by	Checked by	Approved by	Approved by
Sign & Date				
Designation	Executive - PDD	Sr. Manager - PDD	Regulatory Affairs	V. P. (Supply Chain)