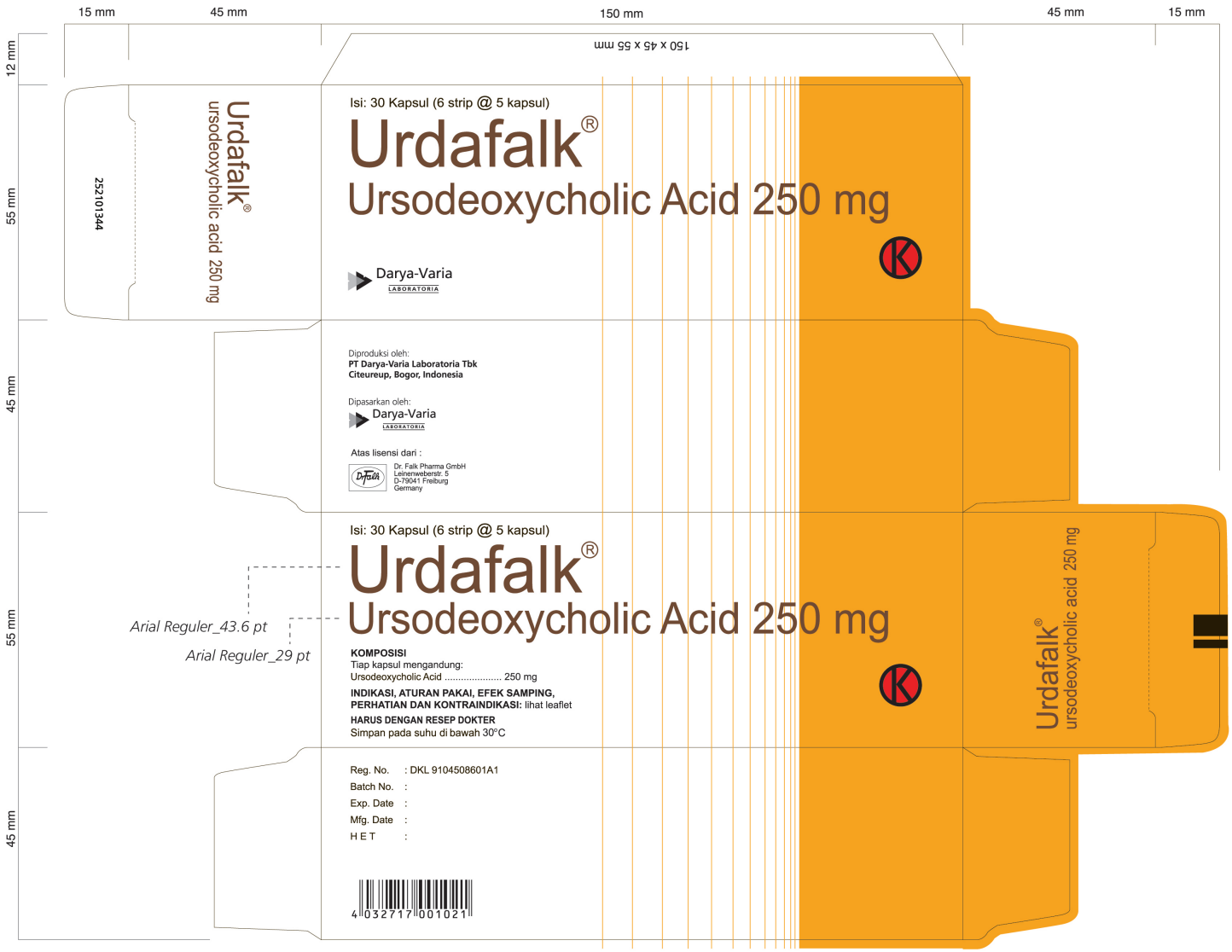


Date	: 19-05-2016	Note	: re_design
Product	: BOX4 URDAFALK SS ID		
Material	: DC 310g		
Dimensi	: 150 X 45 X 55 MM		
Color	: C41.1 M64.7 Y99 K37 Pantone 485 C		
	C1.1 M41 Y99 K0 Pantone Black C		

Drawing by : YS / PMQC DVL Citeureup Plant

Approved by :	Remarks :
QA/QC	
HRA	
MARKETING	

DISETUJUI OLEH BPOM
27 SEPTEMBER 2019

ID REG : EREG100087VR11900123 &
EREG100087I11900122

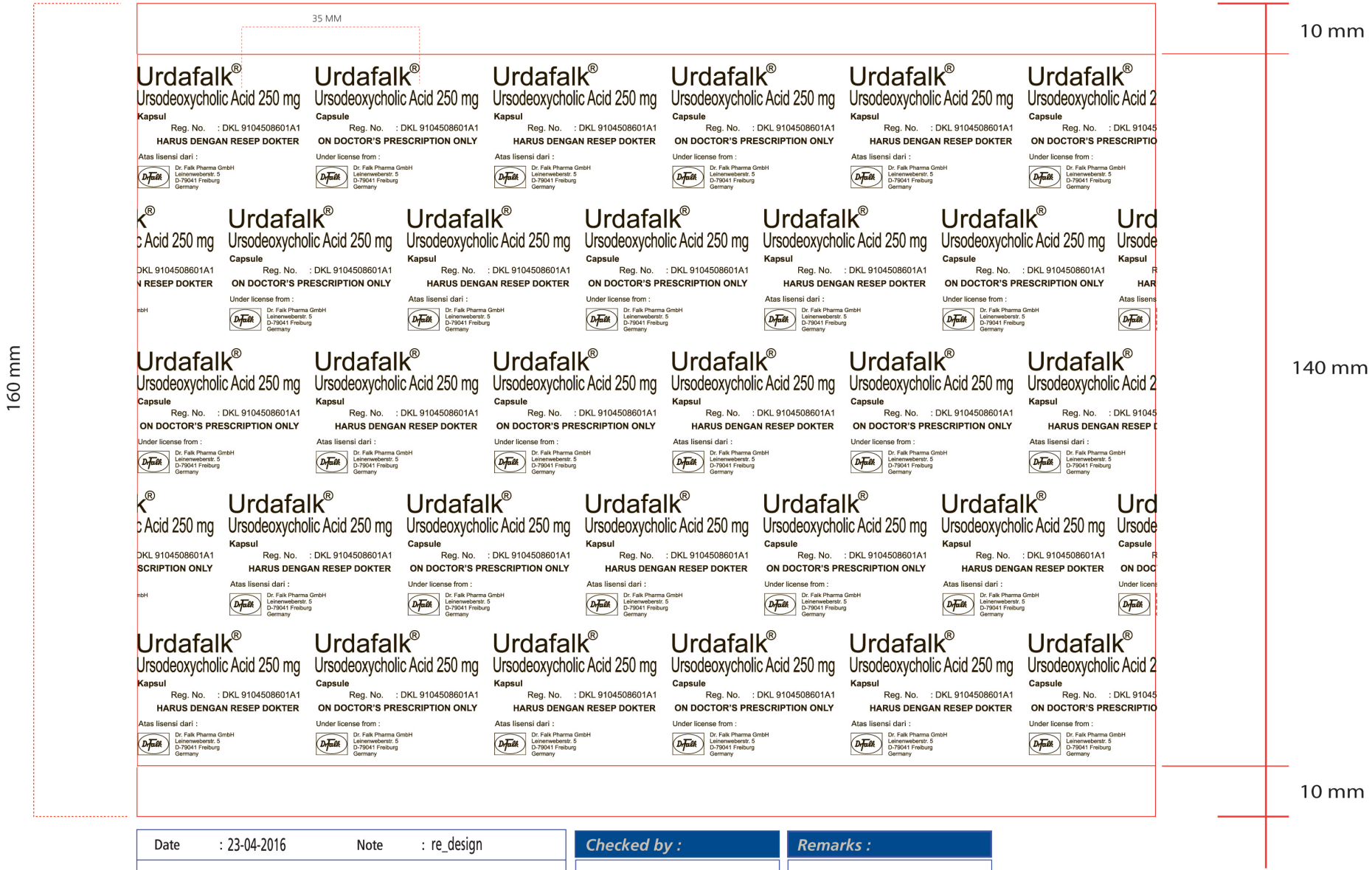
Date	: 19-05-2016	Note	: re_design
Product	: BF12 URDAFALK CAPSULE 160 MM SS ID		
Material	: MST22/PE20/AL15/PE30		
Dimensi	: 160 MM X 500 M		
Color	: Pantone 288 C		

Drawing by : YS / PMQC DVL Citeureup Plant

Approved by :	Remarks :
QA/QC	
HRA	
MARKETING	

DISETUJUI OLEH BPOM
27 SEPTEMBER 2019

ID REG : EREG100087VR11900123 &
EREG10008711900122



Date	: 23-04-2016	Note	: re_design
Product	: FF11 URDAFALK CAPSULE 160 MM SS ID		
Material	: MST22/PE20/AL15/PE30		
Dimensi	: 160 MM X 500 M		
Color	: Pantone Black C		

Drawing by : YS / PMQC DVL Citeureup Plant

Checked by :

Approved by :

Remarks :

Urdafalk® — *Arial Reguler_14.5 pt*
Ursodeoxycholic Acid 250 mg — *Arial Reguler_11.6 pt*

DISETUJUI OLEH BPOM
27 SEPTEMBER 2019

ID REG : EREG10008711900123 &
EREG10008711900122

70 mm

265 mm

Urdafalk®
Ursodeoxycholic Acid 250 mg
kapsul

KOMPOSISI
Tiap kapsul mengandung:
Ursodeoxycholic Acid .....250 mg

FARMAKOLOGI
Urdafalk® mengandung Ursodeoxycholic Acid yang bekerja dengan cara:
Mengubah "precipitate" kolesterol menjadi kolesterol yang mudah larut sehingga mengalami disolusi (mencair) dengan jalan merangsang pembentukan lapisan cair lecithin kolesterol (a lecithin cholesterol liquid layer) pada permukaan batu.
Penekanan terhadap asam-asam empedu endogen yang merangsang hepatotoksisitas (efek langsung), efek sitoprotektif langsung terhadap sel-sel hepatosit dan modifikasi dari sistem imun.
Urdafalk® yang bersifat hidrofilik memiliki efek detergen yang minimal, dengan cara berikatan dengan membran plasma.
Efek imunomodulator ditunjukkan dengan menurunkan ekspresi abnormal HLA, pada hepatosit.
Pemberian Urdafalk® pada penderita refluks gastritis menyebabkan konsentrasi dalam getah lambung meningkat sehingga dapat menetralisir asam empedu yang agresif.

INDIKASI
- Penderita batu empedu tembus sinar X dengan diameter tidak lebih dari 20 mm.
- Penderita yang mempunyai resiko tinggi atau yang menolak untuk operasi kandung empedu.
- Penyakit hati kolestatik.

POSOLOGI
8 - 10 mg / kg bobot badan / hari dibagi dalam 2 atau 3 dosis, diminum dengan susu atau makanan (biasanya diberikan 250 mg pada waktu pagi dan sore hari).
Obat harus diminum secara teratur bila pengobatan dengan Ursodeoxycholic Acid ingin berhasil. Interupsi pemberian Ursodeoxycholic Acid selama 4 minggu berarti pengobatan harus dimulai lagi dari semula.

PERINGATAN DAN PERHATIAN
- Pengobatan batu empedu memerlukan waktu berbulan-bulan, oleh karena itu pemakaian Ursodeoxycholic Acid harus berhati-hati dan harus dipertimbangkan terapi alternatif.
- Proses pelarutan terjadi tidak sempurna pada semua pasien dan lebih dari 50 % pasien akan mengalami pengulangan batu empedu dalam 5 tahun.
- Tidak dianjurkan untuk ibu hamil dan yang sedang menyusui.
- Efektifitas dan keamanan pemakaian pada anak-anak belum dapat diketahui dengan pasti.

EFEK SAMPING
Terjadi diare, pruritus, ruam kulit, urtikaria, kulit kering, keringat dingin, rambut rontok, mual, muntah, gangguan pencernaan makanan, rasa metal, sakit perut, nyeri biliar, kolesistitis, konstipasi, radang mulut, perut kembung, pusing, letih, ansietas, depresi, gangguan tidur, nyeri sendi, nyeri otot, nyeri punggung, batuk dan radang selaput lendir hidung, kalsifikasi batu empedu.

KONTRAINDIKASI
- Batu kolesterol yang mengalami kalsifikasi, batu radiopak, batu radiolusen, pigmen empedu.
- Kolesistitis akut yang tidak mengalami remisi, kolangitis, obstruksi biliar batu pankreas atau fistula biliar gastro-intestinal.
- Obstruksi saluran empedu.
- Kehamilan.
- Pasien dengan kalsifikasi batu empedu.
- Kandung empedu tidak berfungsi.
- Penyakit peradangan dan kelainan pada usus halus.
- Hati dan usus yang dipengaruhi oleh sirkulasi enterohepatik garam empedu.

INTERAKSI OBAT
Cholestyramine atau aluminium hydroxide menghambat penyerapan Ursodeoxycholic Acid.
Pemberian Estrogen, kontrasepsioral dan clofibrate (dan obat-obat penurun kadar lipid yang lain) dapat meningkatkan sekresi kolesterol hati dan mendorong pembentukan batu empedu kolesterol sehingga dapat melawan efektifitas Urdafalk®.

Pemeriksaan Laboratorium:
Dianjurkan untuk melakukan pemeriksaan fungsi hati secara umum (transaminase, bilirubin, alkaline phosphate) pada tiga bulan pertama setiap dua minggu, kemudian setiap tiga minggu.

Lama Pengobatan:
Waktu melarut batu empedu kolesterol yang murni biasanya 6 bulan hingga 2 tahun. Untuk pengontrolan apakah pengobatan berhasil, harus dilakukan penyinaran sinar X terhadap saluran empedu. Apabila tidak ada efek melarut atau pengecilan dari batu empedu setelah 2 tahun, pengobatan selanjutnya tidak berguna lagi.

HARUS DENGAN RESEP DOKTER
Simpan pada suhu di bawah 30°C

KEMASAN
Box isi 30 kapsul dalam 6 strip @ 5 kapsul
No. Reg.: DKL 9104508601A1

Diproduksi oleh:
PT Darya-Varia Laboratoria Tbk
Citeureup, Bogor, Indonesia

Atas lisensi dari :
DR. FALK PHARMA GmbH
Leinenweberstr. 5
D-79041 Freiburg
Germany

Dipasarkan oleh:
Darya-Varia LABORATORIA

251101344

Urdafalk®
Ursodeoxycholic Acid 250 mg
capsule

COMPOSITION
Each capsule contains:
Ursodeoxycholic Acid .....250 mg

PHARMACOLOGY
Urdafalk® contains Ursodeoxycholic Acid that work with: Converts cholesterol precipitates: into readily soluble cholesterol by forming a lecithin cholesterol liquid layer on the surface of gallstones. Ursodeoxycholic Acid suppresses hepatotoxicity induced by endogenous bile acids, has a cytoprotective effect to hepatocyte cells and modification from immune system. The hydrophilic Ursodeoxycholic Acid has detergent effect bind with plasma membrane Immunomodulatory effect showed with reduce the abnormal expression of HLA in hepatocyte. Administration Urdafalk® in patient with gastritis reflux may increase concentration in gastric secrete so that neutralizing aggressive bile acid.

INDICATIONS
- Radiolucents gallstones not exceeding 20 mm in diameter.
- Patients who are at increased risk or who refuse cholecystectomy.
- Liver cholestatic disease.

DOSAGE AND ADMINISTRATIONS
8 - 10 mg / kg body weight / day in 2 or 3 divided doses, taken with milk or meal (usually 250 mg is given in the morning and in the afternoon).
Urdafalk® capsules must be taken regularly to ensure success. Therapy should be reinstituted from the beginning if there is an interruption for 4 weeks.

WARNING AND PRECAUTIONS
- Gallbladder stone dissolution with Ursodeoxycholic Acid requires months of therapy. Therefore, caution should be exercised during therapy with Ursodeoxycholic Acid and alternative therapies should be considered.
- Complete dissolution does not occur in all patients and recurrence of stones within 5 years has been observed in up to 50% of patient.
- Ursodeoxycholic acid is not recommended for pregnant and nursing mothers.
- The safety and effectiveness of Ursodeoxycholic Acidin children have not been established.

SIDE EFFECTS
Side effects include diarrhea, pruritus, skin rash, urticaria, dry skin, cold sweat, hair loss, nausea, vomiting, indigestion, metallic taste, abdominal pain, biliary pain, cholecystitis, constipation, stomatitis, flatulence, dizziness, fatigue, anxiety, depression, sleep disolder, arthtralgia, myalgia, back pain, cough, and rhinitis, gallstone calcification.

CONTRAINDICATIONS
- Calcified cholesterol stones, radiopaque stones or radiolucent bile pigment stones.
- Unremitting acute cholecystitis, cholangitis, biliary obstruction, pancreatitis or biliary gastrointestinal fistula.
- Bile tract obstruction.
- Pregnancy.
- Gallstone calcification.
- Non-functioning gall bladder.
- Inflammatory diseases and other conditions of the small intestine.
- Colon and liver which interfere with entero hepatic circulation of bile salts.

DRUG INTERACTIONS
Cholestyramine or Aluminium hydroxide block the absorption of Ursodeoxycholic Acid.
Estrogen, oral contraceptives and clofibrate (and perhaps other lipid-lowering drugs) increase hepatic cholesterol secretion, and encourage cholesterol gallstone formation and hence may counteract the effectiveness of Urdafalk®.

Laboratory monitor:
Current scientific findings suggest that during the first three months of treatment for gallstone dissolution, the routine function tests (serum levels of transaminases, bilirubin and alkaline phosphate) should be determined fortnightly. Later these tests need to be carried out every three weeks.

Duration of treatment:
Pure cholesterol gallstone dissolve after a period of 6 month to years. To ensure the success of therapy, bile ducts should be monitored by X-ray, if there is no change in gallstone size after 2 years, further treatment will not give good result.

ON DOCTOR'S PRESCRIPTION ONLY
Store below 30°C

PRESENTATION
Box of 30 capsules in 6 strips of 5 capsules
Reg. No.: DKL 9104508601A1

Manufactured by:
PT Darya-Varia Laboratoria Tbk
Citeureup, Bogor, Indonesia

Under license from:
DR. FALK PHARMA GmbH
Leinenweberstr. 5
D-79041 Freiburg
Germany

Marketed by:
Darya-Varia LABORATORIA

Urdafalk®
Ursodeoxycholic Acid 250 mg

Frutiger 65Bold_16.0pt
Frutiger 65Bold_12.8pt (80%)

Date	: 19-05-2016	Note	: re_design
Product	: IN4 URDAFALK SS ID		
Material	: HVS 60g		
Dimensi	: 70 X 265 MM		
Color	: Pantone Black C		

Drawing by : YS / PMQC DVL Citeureup Plant

Approved by :	*Remarks :*
QA/QC	
HRA	
MARKETING	

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27 SEPTEMBER 2019

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