Template Felleskatalog text

Product name **«Company name»**	Product name and company name (as shown on the outer package).
ATC-nr.: N05A A15	ATC code according to WHO index.
T	Reimbursement (we get this information directly from FEST[1]).
▼	Medicines under additional monitoring (according to EMA).
△	Warning against use by drivers of motor vehicles. We get this information directly from FEST[1].
A, B, C, CF, F	Prescription status. We get this information directly from FEST[1].
Antipsykotikum.	Short description of therapeutic classification.
TABLETTER, filmdrasjerte ***10 mg og 20 mg:***	Pharmaceutical form as given in the approved SPC.

Declaration of ingredients	List the ingredients in Norwegian (not Latin). For parenteral products, topical products and ophthalmic products you must list <u>all</u> excipients. For all other pharmaceutical forms: List only lactose, aspartame, phenylalanine, soy products (example soy lecithin), colouring agents and preservatives. Remember the colouring agent in capsules. You shall write the European code (E number) for preservatives and colouring agents in brackets. Furthermore, state a) use of sugar as sweetening agent in tablets and lozenges for chewing or sucking, and oral mixtures, («contains sugar» is sufficient) and b) flavour of mixtures.
Indikasjoner: ***Reseptfri bruk:***	Give the range of indications, as approved in the SPC. Highlight nonprescription use under the subsection “Reseptfri bruk”.

Dosering: ***Indikasjon:*** *Voksne:* *Barn:* ***Spesielle pasientgrupper:*** *Nedsatt lever- og nyrefunksjon:* *Nedsatt leverfunksjon:* *Nedsatt nyrefunksjon:* *Barn og ungdom:* *Eldre:* *Annet:* ***Tilberedning/Håndtering:*** ***Administrering:***	Normal dosage and duration of treatment. Dosage in renal impairment. Dosage for children and the elderly. Method for dosage titration, if relevant. If dose schedules vary considerably from one patient to another, this is to be stated. ***Administration:*** If you must swallow the tablet/capsule whole or if you can chew the tablet/capsule. State reason for this, for example, an unpleasant taste. Administration in relation to meals.
Kontraindikasjoner:	Only absolute contraindications, according to the approved SPC
Forsiktighetsregler: *Hjerte:* *Lunger:* *Hjelpestoffer:* *Bilkjøring og betjening av maskiner:*	Precautions. Don't include descriptions of clinical studies, only include the conclusions. Include only information of side effects if relevant as a precaution. Include warning against use by drivers of motor vehicles at the end of the section.
Interaksjoner:	Include particularly important interactions. On our website, we show information from FEST[1] about interactions at the end of this section.
Graviditet, amming og fertilitet: *Graviditet:* *Amming:* *Fertilitet:*	Use the division in left column when suited. ***Fertility:*** Capacity for reproduction. Give information about prevention of pregnancy under the subsection 'Graviditet'.
Bivirkninger: *Svært vanlige (≥1/10):*	Use the classification in the left column.

Vanlige (≥1/100 til <1/10): *Mindre vanlige (≥1/1000 til <1/100):* *Sjeldne (≥1/10 000 til <1/1000):* *Svært sjeldne (<1/10000), ukjent:* Blod/lymfe Endokrine: Gastrointestinale: Hjerte/kar: Hud: Immunsystemet: Infeksiøse: Kjønnsorganer/bryst: Lever/galle: Luftveier: Medfødte og genetiske sykdommer: Muskel-skjelettsystemet: Nevrologiske: Nyre/urinveier: Psykiske: Stoffskifte/ernæring: Svangerskap: Svulster/cyster: Undersøkelser: Øre: Øye: Øvrige:	If it's not possible to state frequency, you should use the organ classification. If possible, avoid expressions like «is reported», «in some cases», «are not seen» etc. Don't use tables in this section.
Overdosering/ Forgiftning: *Symptomer:* ..... . *Behandling:*	Toxicological information. Estimated dose that gives symptoms of poisoning in adults and children. Use of specific antidote. Whenever possible our editorial staff will add a referral to the section «Poisoning».

Egenskaper: *Klassifisering:* *Virkningsmekanisme:* *Absorpsjon:* *Proteinbinding:* *Fordeling:* *Halveringstid:* *Terapeutisk serumkonsentrasjon:* *Metabolisme:* *Utskillelse:*	Include <u>only</u> information of <u>practical</u> interest. Don't include descriptions of clinical trials. *Classification:* Give a short description of therapeutic use. *Mode of action:* How drugs act, general principles. *Absorption:* Rate of absorption, bioavailability (first pass metabolism). *Protein binding:* Binding to plasma proteins. *Distribution:* Volume of distribution (litre). *Half-life:* Half-life, durability, steady state and clearance (ml/minute). *Therapeutic serum concentration:* Include this only when the effect of the drug is dependent of serum concentration. *Metabolism:* Include only information about pharmacologically active drug metabolites. *Elimination:* Renal and biliary excretion.
Oppbevaring og holdbarhet:	Normally you should not include information about storage and durability instructions, with the exception of special precautions once a product has been opened/made ready for use.
Andre opplysninger:	For example interference with laboratory tests.
Utlevering:	Information about special restrictions regarding distribution, given by the Government.
Reseptfrie pakninger:	Information about nonprescription packages.
Pakninger, priser og	Packages, reimbursement, and prices. We get information about reimbursement and prices directly from FEST[1].

refusjon: **Byttegruppe:**	***Byttegruppe:*** We show information about 'Byttegruppe' only on the website.

[1]FEST: Data form the Norwegian Medicines Agency. Updated 1th and 15th every month.

Template Factual text

Factual text is possible to use for those products where it is possible to refer to a complete Felleskatalog text. The complete Felleskatalog text must give information about the same substance and with same pharmaceutical formulation and strength.

Product name **«Company name»**	Product name and company name (as shown on the outer package).
ATC-nr.: N05A A15	ATC code according to WHO index.
T	Reimbursement (we get this information directly from FEST[1]).
▼	Medicines under additional monitoring (according to EMA).
△	Warning against use by drivers of motor vehicles. We get this information directly from FEST[1].
A, B, C, CF, F	Prescription status. We get this information directly from FEST[1].
Antipsykotikum.	Short description of therapeutic classification.
TABLETTER, filmdrasjerte ***10 mg og 20 mg:***	Pharmaceutical form as given in the approved SPC.

Declaration of ingredients	List the ingredients in Norwegian (not Latin). For parenteral products, topical products and ophthalmic products you must list <u>all</u> excipients. For all other pharmaceutical forms: List only lactose, aspartame, phenylalanine, soy products (example soy lecithin), colouring agents and preservatives. Remember the colouring agent in capsules. You shall write the European code (E

	number) for preservatives and colouring agents in brackets. Furthermore, state a) use of sugar as sweetening agent in tablets and lozenges for chewing or sucking, and oral mixtures, («contains sugar» is sufficient) and b) flavour of mixtures.
Indikasjoner: ***Reseptfri bruk:***	Give the range of indications, as approved in the SPC. Highlight nonprescription use under the subsection "Reseptfri bruk".
Dosering: ***Administrering:***	***For tablets and capsules only:*** ***Administration:*** If you must swallow the tablet/capsule whole or if you can chew the tablet/capsule. State reason for this, for example, an unpleasant taste. Administration in relation to meals.
Utlevering:	Information about special restrictions regarding distribution, given by the Government.
Reseptfrie pakninger:	Information about nonprescription packages.
Pakninger, priser og refusjon: **Byttegruppe:**	Packages, reimbursement, and prices. We get information about reimbursement and prices directly from FEST[1]. ***Byttegruppe:*** We show information about 'Byttegruppe' only on the website.
Preparatreferanse:	Referral to product with complete Felleskatalog text.

[1]FEST: Data form the Norwegian Medicines Agency. Updated 1th and 15th every month.

Tables in general:

You can use tables in all sections, except for the section Side effects (Bivirkninger).

Write footnote as number, and without brackets.

Don't use bold italic in tables.