

## Doravirine Conversions and Quantities

1. To produce Pifeltro, Doravirine API gets transformed into SDI, then formulated into Bulk tablets, and then packaged into finished goods (FiGo)
2. To produce Delstrigo, Doravirine API gets transformed into SDI, then combined with Lamivudine API and Tenofovir API when formulated into Bulk, and then packaged into finished goods (FiGo)
3. TS is the standard unit of measurement for Bulk and it stands for Thousand Tablets, therefore 1 TS equals 1000 tabs/tablets
4. KG is the standard unit of measurement for SDI and API
5. EA (units) is the standard unit of measurement for finished goods (FiGo)
6. The MOQ for Tenofovir API is 1600 KG
7. The MOQ for Lamivudine API is 1200 KG
8. The MOQ for FIS Doravirine API is 320 KG
9. The MOQ for Ballydine Doravirine API is 196.5 KG
10. API is produced 1-2 annually and can be produced either at Ballydine or at FIS
11. API from either source is then converted into SDI at either FIS or Hovione
12. 1 batch of Hovione SDI is 460 KG
13. 1 batch of FIS SDI is 360 KG
14. 0.211 KG of Doravirine API are needed to make 1 KG of Doravirine SDI
15. Hovione SDI has a minimum of 6 batches per campaign, a maximum of 9 batches per campaign, batches produced per campaign must be in multiples of 3, and a maximum of 3 campaigns per year
16. FIS SDI has a minimum of 4 batches per campaign and they produce every 1-2 months
17. SDI from either source is then moved to Ballydine to formulate Pifeltro and Delstrigo Bulk
18. The minimum order quantity (MOQ) of Pifeltro Bulk is one batch which equals 176.5 TS
19. One batch of Pifeltro Bulk is weighing 182 KG of which 19 KG are of Doravirine API
20. The minimum order quantity of Delstrigo Bulk is one batch which equals 450 TS
21. One batch of Delstrigo Bulk is weighing 714 KG of which 56 KG are Doravirine API, 150 KG are Lamivudine API, and 150 KG are Tenofovir API
22. Bulk at Ballydine produces once per quarter, and Delstrigo Bulk has a maximum of 21 batches per campaign
23. Finished goods are packed monthly at Haarlem
24. One unit (EA) of Pifeltro or Delstrigo finished goods (FiGo) has 30 tablets

## Doravirine Supply Chain Map

- Two main intermediates are used to make Doravirine API, those being HMT (HYDROXY METHYL TRIAZOLINONE) and Pyridone
- Because FIS is an external third-party supplier, they source their own raw materials, intermediates, and produce their own API
- Ballydine sources intermediate HMT from Divis and produces Pyridone internally on-site
- We have two sources of Doravirine API, Ballydine and FIS
- Ballydine Doravirine API is material number 2012530 and material description is “DORAVIRINE”
- FIS Doravirine API is material number 2019247 and material description is “DORAVIRINE (FIS)”
- Once Doravirine API is produced at either FIS or Ballydine, it must undergo an intermediate step of spray drying that will convert the material from an API to an SDI.
- We have two sources of SDI (spray dry intermediate) being Hovione and FIS (Fabbrica Italiana Sintetici)
- SDI that uses Ballydine API and was spray dried at Hovione is material number 2016804 and has a material description of DORAVIRINE SDI B/B (DIV/HOV)
- SDI that uses Ballydine API and was spray dried at FIS is material number 2015139 and has a material description of DORAVIRINE SDI (BAL/FIS)
- SDI that uses FIS API and was spray dried at FIS is material number 2019847 and has a material description of DORAVIRINE SDI (FIS/FIS)
- If FIS API is sprayed at FIS, it must go to plant 1518 first, it cannot be converted to SDI without doing this movement.
- Pifetro and Delstrigo are Bulk that are produced with Doravirine SDI
- Currently we only have one Bulk formulation site which is Ballydine
- Delstrigo requires two additional APIs which are sourced externally, these are material number 2016523 (material description “LAMIVUDINE RP1”) and either material number 2014291 (material description “TENOFOVIR”) or either material number 2017802 (material description “TENOFOVIR RP1”)
- RP1 means that the Tenofovir that was used is of a chemical composition that has low CMIC
- Material number 2014291 (material description “TENOFOVIR”) is considered high-CMIC
- Doravirine SDI gets formulated into Bulk at Ballydine that can be either Pifetro Bulk or Delstrigo Bulk
- For Pifetro Bulk, the material number and material description are:
  - 2014293 “DORAVIRINE 100 MG” if using Ballydine API and Hovione SDI
  - 2015138 “DORAVIRINE 100MG FCT (FLV/FIS)” if using Ballydine API and Hovione SDI
  - 2021662 “DORAVIRINE 100MG FCT (FIS/FIS)” if using FIS API and FIS SDI
- For Delstrigo Bulk, the material number and material description are:

- 2016753 “DOR/LAM/TDF 100/300/300MG (FLV/HOV)” if produced in the small batch configuration using Ballydine API, Hovione SDI, and high-CMIC Tenofovir. This small batch configuration will no longer be used.
- 2018130 “DOR/LAM/TDF 100/300/300MG TDF RP1” if produced using Ballydine API, FIS SDI, and low-CMIC Tenofovir
- 2021663 “DOR/LAM/TDF 100/300/300MG RP1 (FIS/FIS)” if produced using FIS API, FIS SDI, and low-CMIC Tenofovir
- 2021724 “DOR/LAM/TDF 100/300/300MG B/B (BAL/HOV)” if produced using Ballydine API, Hovione SDI, and high-CMIC Tenofovir
- 2021848 “DOR/LAM/TDF 100/300/300 B/B (BAL/HOV)RP1” if produced using Ballydine API, Hovione SDI, and low-CMIC Tenofovir
- Bulk is packaged at Haarlem, Netherlands for Europe, Europe-like, Latin America, Russia, Asia Pacific and other EMEA markets.
- Wilson, US, packs for only for US and Canada and no other markets.
- Pandaan, Indonesia packs for AP markets
- And Menuma, Japan packs for Japan and only Japan.

**As of January 2025, the following SKU were available by the following markets:**

1. For the USA:
  - SKU/Material Number: 1038220, Name: PIFELTRO 100MG 30TAB BOTTLE
  - SKU/Material Number: 1038616, Name: DELSTRIGO 100/300/300MG 30TAB BOTTLE
2. For Canada:
  - SKU/Material Number: 1039466, Name: PIFELTRO 100MG 30TAB BOTTLE
  - SKU/Material Number: 1039467, Name: DELSTRIGO 100/300/300MG 30TAB BOTTLE
3. For Belgium, Austria, and the Netherlands:
  - SKU/Material Number: 1039479, Name: PIFELTRO 100MG 30TAB L19
  - SKU/Material Number: 1039608, Name: DELSTRIGO 100/300/245MG 30TAB L19
4. For Germany:
  - SKU/Material Number: 1039526, Name: DELSTRIGO 100/300/245MG 30TAB
  - SKU/Material Number: 1039544, Name: PIFELTRO 100MG 30TAB
  - SKU/Material Number: 1039569, Name: DELSTRIGO 100/300/245MG 3X30TAB
  - SKU/Material Number: 1039598, Name: PIFELTRO 100MG 3X30TAB
5. For Spain:
  - SKU/Material Number: 1039596, Name: PIFELTRO 100MG 30TAB ESP
6. For the United Kingdom:
  - SKU/Material Number: 1039606, Name: PIFELTRO 100MG 30TAB GBR
  - SKU/Material Number: 1039624, Name: DELSTRIGO 100/300/245MG 30TAB GBR
7. For Sweden and Finland:
  - SKU/Material Number: 1039658, Name: PIFELTRO 100MG 30TAB SWE/FIN
  - SKU/Material Number: 1039904, Name: DELSTRIGO 100/300/245MG 30TAB SWE/FIN
8. For Norway and Denmark:
  - SKU/Material Number: 1039836, Name: DELSTRIGO 100/300/245MG 30TAB L74
9. For Lithuania:
  - SKU/Material Number: 1039912, Name: DELSTRIGO 100/300/245MG 30TAB BAL
  - SKU/Material Number: 1042214, Name: PIFELTRO 100MG 30TAB BAL

10. For Switzerland:

- SKU/Material Number: 1039949, Name: PIFELTRO 100MG 30TAB CHE
- SKU/Material Number: 1041294, Name: DELSTRIGO 100/300/245MG 30TAB CHE

11. For Portugal and Belgium:

- SKU/Material Number: 1040064, Name: PIFELTRO 100 MG 30TAB LN4
- SKU/Material Number: 1041134, Name: DELSTRIGO 100/300/245MG 30TAB LN4

12. For France:

- SKU/Material Number: 1041145, Name: PIFELTRO 100MG 30TAB FRA
- SKU/Material Number: 1041274, Name: DELSTRIGO 100/300/245MG 30TAB FRA

13. For Italy:

- SKU/Material Number: 1041146, Name: DELSTRIGO 100/300/245MG 30TAB ITA
- SKU/Material Number: 1041257, Name: PIFELTRO 100MG 30TAB ITA

14. For Russia:

- SKU/Material Number: 1041258, Name: PIFELTRO 100MG 30TAB RUS
- SKU/Material Number: 1042154, Name: DELSTRIGO 100/300/245MG 30TAB RUS

15. For Saudi Arabia:

- SKU/Material Number: 1041617, Name: PIFELTRO 100MG 30TAB SAU
- SKU/Material Number: 1041637, Name: DELSTRIGO 100/300/300MG 30TAB SAU

16. For Greece:

- SKU/Material Number: 1041768, Name: DELSTRIGO 100/300/245MG 30TAB GRC
- SKU/Material Number: 1042019, Name: PIFELTRO 100MG 30TAB GRC/CYP

17. For Chile:

- SKU/Material Number: 1041824, Name: DELSTRIGO 100/300/300MG 30TAB CHL

18. For Argentina:

- SKU/Material Number: 1041825, Name: DELSTRIGO 100/300/245MG 30TAB ARG
- SKU/Material Number: 1041932, Name: PIFELTRO 100MG 30TAB ARG

19. For Colombia:

- SKU/Material Number: 1042225, Name: PIFELTRO 100MG 30TAB COL
- SKU/Material Number: 1042235, Name: DELSTRIGO 100/300/300MG 30TAB COL

20. For Algeria:

- SKU/Material Number: 1042547, Name: DELSTRIGO 100/300/300MG 30TAB DZA
- SKU/Material Number: 1042587, Name: PIFELTRO 100MG 30TAB DZA

21. For Hungary and Romania:

- SKU/Material Number: 1042590, Name: DELSTRIGO 100/300/245MG 30TAB L93
- SKU/Material Number: 1042619, Name: PIFELTRO 100MG 30TAB L93

22. For China:

- SKU/Material Number: 1042894, Name: PIFELTRO 100MG 30TAB CHN
- SKU/Material Number: 1042914, Name: DELSTRIGO 100/300/300MG 30TAB CHN

23. For Hong Kong:

- SKU/Material Number: 1042915, Name: DELSTRIGO 100/300/300MG 30TAB HKG

24. For Taiwan:

- SKU/Material Number: 1043764, Name: DELSTRIGO 100/300/300MG 30TAB TWN

25. For South Korea:

- SKU/Material Number: 1043925, Name: PIFELTRO 100MG 30TAB KOR
- SKU/Material Number: 1043974, Name: DELSTRIGO 100/300/300MG 30TAB KOR

26. For South Africa:

- SKU/Material Number: 1046518, Name: PIFELTRO 100MG 30TAB ZAF
- SKU/Material Number: 1046865, Name: DELSTRIGO 100/300/245MG 30TAB ZAF

27. For the United Arab Emirates and Lebanon:

- SKU/Material Number: 1048278, Name: DELSTRIGO 100/300/245MG 30TAB L25
- SKU/Material Number: 1048279, Name: PIFELTRO 100MG 30TAB L25

28. For Kuwait:

- SKU/Material Number: 1049638, Name: DELSTRIGO 100/300/245MG 30TAB L25 (HLM)
- SKU/Material Number: 1049639, Name: PIFELTRO 100MG 30TAB L25 (HLM)

29. For Turkey:

- SKU/Material Number: 1050325, Name: DELSTRIGO 100/300/300MG 30TAB TUR