Public Assessment Report

UKPAR

SILDENAFIL 20MG FILM-COATED TABLETS

(Sildenafil citrate)

UK Licence No: PL 36722/0100

Special Concept Development (UK) Limited (trading as Rx Farma)
**LAY SUMMARY**

Sildenafil 20 mg film-coated tablets
(sildenafil citrate)

This is a summary of the Public Assessment Report (PAR) for Sildenafil 20 mg film-coated tablets (PL 36722/0100). It explains how the application for Sildenafil 20 mg film-coated tablets was assessed and their authorisation recommended as well as their conditions of use. It is not intended to provide practical advice on how to use Sildenafil 20 mg film-coated tablets.

For practical information about using Sildenafil 20 mg film-coated tablets, patients should read the package leaflet or contact their doctor or pharmacist.

For ease of reading, this product will be referred to as Sildenafil tablets for the remainder of this summary.

**What are Sildenafil tablets and what are they used for?**

Sildenafil tablets are a ‘generic medicine’. This means that Sildenafil tablets are similar to a ‘reference medicine’ already authorised in the European Union (EU) called Revatio 20 mg film-coated tablets.

Sildenafil tablets are used to treat adults and children and adolescents from 1 to 17 years old with high blood pressure in the blood vessels in the lungs (pulmonary arterial hypertension).

**How do Sildenafil tablets work?**

This medicine contains the active ingredient sildenafil, which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. It works by widening the blood vessels in the lungs, which brings down the blood pressure in the lungs.

**How are Sildenafil tablets used?**

This medicine can only be obtained with a prescription.

For adults, the recommended dose is 20 mg three times a day (taken 6 to 8 hours apart) taken with or without food.

For children and adolescents aged 1 year to 17 years old, the recommended dose is either 10 mg three times a day for children and adolescents ≤20 kg or 20 mg three times a day for children and adolescents >20 kg, taken with or without food.

Higher doses should not be used in children. This medicine should be used only in case of administration of 20 mg three times a day. Other pharmaceutical forms may be more appropriate for administration to patients ≤ 20 kg and other younger patients who are not able to swallow tablets.

**What benefits of Sildenafil tablets have been shown in studies?**

Because Sildenafil tablets are a generic medicine, studies in patients have been limited to tests to determine that they are bioequivalent to the reference medicines, Revatio 20 mg film-coated tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

**What are the possible side effects of Sildenafil tablets?**

Because Sildenafil tablets are a generic medicine, their possible side effects are taken as being the same as those of the reference medicine, Revatio 20 mg film-coated tablets.

For the full list of all side effects reported with Sildenafil tablets, see section 4 of the package leaflet.
For the full list of restrictions, see the package leaflet.

**Why were Sildenafil tablets approved?**
It was concluded that, in accordance with EU requirements, Sildenafil tablets have been shown to have comparable quality and to be bioequivalent to Revatio 20 mg film-coated tablets. Therefore, the MHRA decided that, as for Revatio 20 mg film-coated tablets, the benefits outweigh the identified risks and recommended that Sildenafil tablets can be approved for use.

**What measures are being taken to ensure the safe and effective use of Sildenafil tablets?**
A risk management plan (RMP) has been developed to ensure that Sildenafil tablets are used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics (SmPC) and the package leaflet for Sildenafil tablets including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored and reviewed continuously.

**Other information about Sildenafil tablets**
Marketing Authorisations were granted in the UK on 12 January 2018.

The full PAR for Sildenafil tablets follows this summary. For more information about treatment with Sildenafil tablets read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in January 2018.
SCIENTIFIC DISCUSSION

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I INTRODUCTION
Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) granted Special Concept Development (UK) Limited, a Marketing Authorisation for the medicinal product Sildenafil 20 mg film-coated tablets (PL 36722/0100) on 12 January 2018.

This product is a prescription-only medicine (legal classification POM).

This application was made according to Article 10(1) of Directive 2001/83/EC, as amended. The reference product for is Revatio 20mg film-coated tablets, which was granted a Marketing Authorisation to Pfizer Limited, via the Centralised procedure, on 05 October 2005. The medicinal product to which bioequivalence has been tested is Viagra Tablets 100 mg (Pfizer Limited).

Sildenafil 20 mg film-coated tablets are indicated for the treatment of adult patients with pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease.

Sildenafil 20 mg film-coated tablets are also indicated for treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension with congenital heart disease.

This product contains the active substance sildenafil citrate. Sildenafil is a potent and selective inhibitor of cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type 5 (PDE5), the enzyme that is responsible for degradation of cGMP. Apart from the presence of this enzyme in the corpus cavernosum of the penis, PDE5 is also present in the pulmonary vasculature. Sildenafil, therefore, increases cGMP within pulmonary vascular smooth muscle cells resulting in relaxation. In patients with pulmonary arterial hypertension this can lead to vasodilation of the pulmonary vascular bed and, to a lesser degree, vasodilatation in the systemic circulation.

With the exception of the bioequivalence study, no new clinical or non-clinical studies were conducted, which is acceptable given that the application was based on being a generic medicinal product of an originator product that has been licensed for over 10 years.

A bioequivalence study was performed which compared the pharmacokinetics of a higher strength of the test product, Sildenafil 100 mg film-coated tablets, to those of a higher strength of reference product, Viagra Tablets 100 mg (Pfizer Limited).

The MHRA has been assured that acceptable standards of Good Manufacturing Practice are in place for this product type at all sites responsible for the manufacture, assembly and batch release of the product.

A summary of the pharmacovigilance system and a detailed Risk Management Plan (RMP) have been provided with this application and these are satisfactory.
II QUALITY ASPECTS

II.1 Introduction
Sildenafil 20 mg film-coated tablets are white to off white, round, approx. 6.5mm wide, biconvex, film coated tablets debossed with 'J' on one side and '95' on the other side. Each film-coated tablet contains 20 mg of sildenafil (as citrate).

Other ingredients consist of the pharmaceutical excipients, as follows:
Tablet core:
- Microcrystalline cellulose
- Anhydrous calcium hydrogen phosphate
- Croscarmellose sodium
- Magnesium stearate

Film coat:
- Hypromellose (E464)
- Titanium dioxide (E171)
- Lactose monohydrate
- Triacetin

The finished product is packaged in polyvinyl chloride/aluminium and polyvinyl chloride/polyvinylidene chloride/aluminium blister packs containing 30, 90, 300 and 500 film-coated tablets. They are also supplied in high density polyethylene bottles containing 90, 300 and 500 film-coated tablets. Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current European regulations concerning materials in contact with food.

II.2 Drug substance
rINN: Sildenafil Citrate
Structure:

![Sildenafil Citrate Structure](image)

Molecular formula: $C_{28}H_{38}N_{6}O_{11}S$
Molecular weight: 666.7
Appearance: White to off-white crystalline powder
Solubility: Slightly soluble in water and methanol

All aspects of the manufacture and control of the active substance sildenafil citrate are covered by a European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability (CEP).

II.3 Medicinal Product
Pharmaceutical Development
The objective of the development programme was to formulate a stable and robust product that could be considered a generic medicinal product of the currently licensed products, Revatio 20mg film-coated tablets (Pfizer Ltd).
A satisfactory account of the pharmaceutical development has been provided.

Comparative in vitro dissolution profiles have been provided for the applicant’s product versus the reference product and versus Sildenafil 100 mg film-coated tablets, used in the bioequivalence study.

All excipients comply with their respective European Pharmacopoeia monographs.

With the exception of lactose monohydrate, none of the excipients are sourced from animal or human origin. The milk used in the production of lactose monohydrate is sourced from healthy animals under the same conditions as that for human consumption. This product does not contain or consist of genetically modified organisms (GMO).

Manufacturing Process
A satisfactory batch formula has been provided for the manufacture of the product, along with an appropriate description of the manufacturing process. Suitable in-process controls are in place to ensure the quality of the finished product. Process validation has been carried out on two commercial scale batches of finished product. The results are satisfactory.

Finished Product Specification
The finished product specification proposed is acceptable. Test methods have been described and have been adequately validated. Batch data have been provided and comply with the release specification. Certificates of Analysis have been provided for all working standards used.

Stability of the product
Stability studies were performed, in accordance with current guidelines, on batches of finished product in the packaging proposed for marketing.

The results from these studies support a shelf-life of 3 years, with no special storage conditions.

II.4 Discussion on chemical, pharmaceutical and biological aspects
It is recommended that a Marketing Authorisation is granted for Sildenafil 20 mg film-coated tablets.

II NON-CLINICAL ASPECTS

III.1 Introduction
The pharmacodynamic, pharmacokinetic and toxicological properties of sildenafil citrate are well known. No new non-clinical data have been submitted for this application and none are required.

The applicant has provided an overview based on published literature. The non-clinical overview has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the product’s pharmacology and toxicology.

III.2 Pharmacology
No new pharmacology data are required for this application and none have been submitted.

III.3 Pharmacokinetics
No new pharmacokinetic data are required for this application and none have been submitted.

III.4 Toxicology
No new toxicology data are required for this application and none have been submitted.

III.5 Ecotoxicity/Environmental risk Assessment (ERA)
As this product is intended for generic substitution of a product that is already marketed, no increase in
environmental exposure to sildenafil citrate is anticipated. Thus the absence of an ERA is accepted.

III.6 Discussion of the non-clinical aspects
It is recommended that a Marketing Authorisation is granted for Sildenafil 20 mg film-coated tablets.

IV. CLINICAL ASPECTS
IV.1 Introduction
With the exception of the bioequivalence study detailed below, no new clinical studies have been performed and none are required for this type of application. The applicant’s clinical overview has been written by an appropriately qualified person and is considered acceptable.

IV.2 Pharmacokinetics
In support of the application, the applicant submitted the following bioequivalence study:

An open label, balanced, randomised, single-dose, two-treatment, two-sequence, two-period, crossover bioequivalence study comparing the pharmacokinetics of Sildenafil 100 mg film-coated tablets, to those of the reference product, Viagra Tablets 100 mg (Pfizer Limited), in healthy, adult, human subjects, under fasting conditions.

Volunteers were given each treatment after an overnight fast of at least 10 hours. Blood samples were collected for the measurement of pharmacokinetic parameters pre-dose and up to 24 hours post dose. Each treatment was separated by a washout period of 8 days.

A summary of the main pharmacokinetic results for sildenafil and its metabolite N-desmethyl-sildenafil are presented in the tables below:

Pharmacokinetic data for sildenafil

```
<table>
<thead>
<tr>
<th>Pharmacokinetic parameter</th>
<th>Test product</th>
<th>Reference Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC$_{(0-72)}$ (ng hr/mL)</td>
<td>2504.923 ± 982.1009</td>
<td>2523.685 ± 935.5418</td>
</tr>
<tr>
<td>AUC$_{(0-∞)}$ (ng hr/mL)</td>
<td>2549.716 ± 1600.4731</td>
<td>2568.840 ± 981.9569</td>
</tr>
<tr>
<td>C$_{max}$ (ng/mL)</td>
<td>844.675 ± 442.3907</td>
<td>838.801 ± 450.8381</td>
</tr>
<tr>
<td>t$_{max}$ (hr)</td>
<td>1.034 ± 0.7489</td>
<td>1.128 ± 0.8392</td>
</tr>
<tr>
<td>K$_{el}$ (1/hr)</td>
<td>0.164 ± 0.05317</td>
<td>0.1628 ± 0.04408</td>
</tr>
<tr>
<td>t$_{1/2}$ (hr)</td>
<td>4.531 ± 1.0325</td>
<td>4.490 ± 0.9250</td>
</tr>
</tbody>
</table>
```

1. AUC(0-72h) can be reported instead of AUC(0-t), in studies with a sampling period of 72 h, and where the concentration at 72 h is quantifiable. Only for immediate release products.
2. AUC(0-∞) does not need to be reported when AUC(0-72h) is reported instead of AUC(0-t).
3. Median (Min, Max)
4. Arithmetic Means (±SD) may be substituted by Geometric Mean (± CV %)

Pharmacokinetic data for N-desmethyl-sildenafil

```
<table>
<thead>
<tr>
<th>Pharmacokinetic parameter</th>
<th>Test product</th>
<th>Reference Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC$_{(0-72)}$ (ng hr/mL)</td>
<td>544.000 ± 216.0706</td>
<td>523.170 ± 198.3221</td>
</tr>
<tr>
<td>AUC$_{(0-∞)}$ (ng hr/mL)</td>
<td>575.212 ± 225.2489</td>
<td>556.588 ± 207.9429</td>
</tr>
<tr>
<td>C$_{max}$ (ng/mL)</td>
<td>106.929 ± 43.1638</td>
<td>102.931 ± 44.7187</td>
</tr>
<tr>
<td>t$_{max}$ (hr)</td>
<td>1.145 ± 0.6977</td>
<td>1.298 ± 0.7373</td>
</tr>
<tr>
<td>K$_{el}$ (1/hr)</td>
<td>0.1306 ± 0.03058</td>
<td>0.1360 ± 0.03795</td>
</tr>
<tr>
<td>t$_{1/2}$ (hr)</td>
<td>5.579 ± 1.2345</td>
<td>5.447 ± 1.3760</td>
</tr>
</tbody>
</table>
```

1. AUC(0-72h) can be reported instead of AUC(0-t), in studies with a sampling period of 72 h, and where the concentration at 72 h is quantifiable. Only for immediate release products.
Bioequivalence evaluation of sildenafil

<table>
<thead>
<tr>
<th>Pharmacokinetic parameter</th>
<th>Geometric Mean Ratio Test/Ref</th>
<th>Confidence Intervals</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC(0-72h) (hr*ng/mL)</td>
<td>99.67</td>
<td>94.22% - 105.44%</td>
<td>14.81</td>
</tr>
<tr>
<td>C_{max} (ng/mL)</td>
<td>102.57</td>
<td>91.82% - 114.38%</td>
<td>29.60</td>
</tr>
</tbody>
</table>

1. Estimated from the Residual Mean Squares. For replicate design studies report the within subject CV% using only the reference product data.

The 90% confidence intervals for sildenafil for the ratio of test/reference are within 80.00-125.00% for Cmax and AUC. Sildenafil 100 mg film-coated tablets are, therefore, considered bioequivalent to Viagra Tablets 100 mg (Pfizer Limited).

As Sildenafil 20 mg and 100 mg film-coated tablets meet the bio-waiver criteria specified in the Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev.1/Corr**), the results and conclusions of the bioequivalence study on the 100 mg strength can be extrapolated to the 20 mg strength film-coated tablets.

IV.3 Pharmacodynamics
No new pharmacodynamic data were submitted and none are required for applications of this type.

IV.4 Clinical efficacy
No new data on efficacy have been submitted and none are required for applications of this type.

IV.5 Clinical Safety
No new data on safety have been submitted and none are required for applications of this type.

No new or unexpected safety concerns arose from this application.

IV.6 Risk Management Plan (RMP) and Pharmacovigilance System
The Pharmacovigilance System, as described by the applicant, fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance, and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

The MAH has submitted a RMP, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Sildenafil 20 mg film-coated tablets.

A summary of safety concerns and planned risk minimisation activities, as approved in the RMP, are listed below:
<table>
<thead>
<tr>
<th>Safety concern</th>
<th>Routine risk minimisation measures</th>
<th>Additional risk minimisation measures</th>
</tr>
</thead>
</table>
| Drug Interaction with        | Caution should be exercised regarding the co-administration of Sildenafil and with Bosentan (a moderate inducer of CYP3A4, CYP2C9 and possibly of CYP2C19) due to the occurrence of drug interactions, which are known to occur.  
  - Warnings have been provided in SPC section 4.4 4.5 5.1 and PIL section 2  
  Prescription only medicine  | None                                                                                                           |
| Bosentan                     |                                                                                                                                                                                                                                                                                                                                 |                                        |
| Bleeding problems and        | Warning of Sildenafil administration in patients with bleeding disorders or active peptic ulceration (which should only be pursued after careful benefit risk assessment), as no safety information is currently available regarding the use in these patients.  
  - Warnings have been provided in SPC Section 4.4, 4.8 and PIL section 2  
  Listed in SPC section 4.8  
  Prescription only medicine  | None                                                                                                           |
<p>| Epistaxis                     |                                                                                                                                                                                                                                                                                                                                 |                                        |</p>
<table>
<thead>
<tr>
<th>Safety concern</th>
<th>Routine risk minimisation measures</th>
<th>Additional risk minimisation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality increase in paediatric population</td>
<td>Due to an increase in deaths observed in long term paediatric PAH patients studies, in which an increase in deaths was observed, caution is advised against the administration of higher than the recommended doses of Sildenafil in paediatric patients.</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>• Warning is provided in SPC section 4.4 and 5.1 Prescription only medicine</td>
<td></td>
</tr>
<tr>
<td>Vaso-occlusive crisis in sickle cell anaemia patients</td>
<td>Clinical Study evidence exists to support the occurrence of events of vaso-occlusive crises in sickle cell patients, which lead to more hospitalisations. Sildenafil should therefore not be used in patients with Pulmonary Hypertension secondary to Sickle cell anaemia.</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>• Warning is provided in SPC section 4.4 and PIL section 2 Prescription only medicine</td>
<td></td>
</tr>
<tr>
<td>Nitrate interaction</td>
<td>Warning to be aware of the fact that sildenafil has been shown to potentiate the hypotensive effects of nitrates, and therefore its co-administration with nitric oxide donors or nitrates in any form is therefore contraindicated</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>• Warning is provided in SPC section 4.3, 4.5, and PIL section 2 Prescription only medicine</td>
<td></td>
</tr>
<tr>
<td>Hypotension</td>
<td>Warning regarding the co-administration of sildenafil, with guanylate cyclase stimulators, (such as riociguat) which is contraindicated, as it</td>
<td>None</td>
</tr>
<tr>
<td>Safety concern</td>
<td>Routine risk minimisation measures</td>
<td>Additional risk minimisation measures</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>Sildenafil 20 mg film-coated tablets</td>
<td>may potentially lead to symptomatic hypotension</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Warning is provided in section 4.3, 4.4, 4.8 and PIL section 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Listed in SPC section 4.8</td>
<td></td>
</tr>
<tr>
<td>Non-arteritic anterior ischaemic optic neuropathy</td>
<td>Cases of non-arteritic anterior ischaemic optic neuropathy, a rare condition, have been reported spontaneously and in an observational study in connection with the intake of sildenafil and other PDE5 inhibitors.</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>• Warning is provided in SPC section 4.4, 4.8 and PIL Section 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Listed in SPC section 4.8</td>
<td></td>
</tr>
<tr>
<td>Hearing loss</td>
<td>Sildenafil usage has been linked to sudden hearing use.</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>• Warning is provided in SPC section 4.8 and PIL section 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Listed in SPC section 4.8</td>
<td></td>
</tr>
<tr>
<td>Safety concern</td>
<td>Routine risk minimisation measures</td>
<td>Additional risk minimisation measures</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------</td>
</tr>
</tbody>
</table>
| Possible drug interactions with iloprost and epoprostenol | Caution is to be exercised if Sildenafil is coadministered with other treatments for pulmonary hypertension (i.e. iloprost and epoprostenol, as the safety and efficacy has not been investigated or studied in controlled clinical trials and the possibility of drug interactions are likely.  
  - Warning is provided in SPC section 4.4, 4.5, 5.1 and PIL section 2                                                                                           | None                                 |
| Unknown safety and efficacy usage in children under 1 years old | Currently no data exists regarding the safety and efficacy of Sildenafil in children under the age of 1 years old, and therefore its use, in this age group is not recommended.  
  - Warning is provided in SPC section 4.2 and PIL section 2                                                                                                      | None                                 |
| Unknown effect of Sildenafil on mortality           | Current knowledge from numerous Sildenafil PAH patient studies has not confirmed the effect of Sildenafil on mortality and hence this information is still currently unknown.  
  - Warning is provided in SPC section 5.1                                                                            | None                                 |
| Usage in Pregnancy                                 | Due to lack of data on effects of Sildenafil in pregnant women, it is not recommended for women of childbearing age.  
  - Warning is provided in SPC                                                                                                                                          | None                                 |
### IV.7 Discussion of the clinical aspects

It is recommended that a Marketing Authorisation is granted for Sildenafil 20 mg film-coated tablets.

### V. USER CONSULTATION

The package leaflet has been evaluated in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC, as amended. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that patients/users are able to act upon the information that it contains.

### VI OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The data supplied support the claim that the applicant’s product and the reference product are interchangeable. Extensive clinical experience with sildenafil citrate is considered to have demonstrated the therapeutic value of the compound. The benefit-risk assessment is therefore considered to be positive.

#### Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) are provided within the document.
Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The approved labelling for Sildenafil 20 mg film-coated tablets is presented below:
Annex 1  Table of content of the PAR update for MRP and DCP

Steps taken after the initial procedure with an influence on the Public Assessment Report

<table>
<thead>
<tr>
<th>Scope</th>
<th>Procedure number</th>
<th>Product Information affected</th>
<th>Date of start of the procedure</th>
<th>Date of end of procedure</th>
<th>Approval/ non approval</th>
<th>Assessment report attached</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y/N (version)</td>
<td></td>
</tr>
</tbody>
</table>